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may be submitted to the GUDID. We will announce any change on the FDA Web site at *http://www.fda.gov/udi/* at least 60 days before making the change.

§ 830.350 Correction of information submitted to the Global Unique Device Identification Database.

(a) If FDA becomes aware that any information submitted to the Global Unique Device Identification Database (GUDID) appears to be incorrect or potentially misleading, we may notify the labeler of the specific information that appears to be incorrect, and request that the labeler provide corrected information or explain why the information is correct. The labeler must provide corrected information or provide a satisfactory explanation of why the information is correct within 30 days of receipt of FDA's notification.

(b) If the labeler does not respond to FDA's notification within 30 days of receipt, or if FDA determines, at any time, that any information in the GUDID is incorrect or could be misleading, we may delete or correct the information. Any action taken by FDA under this paragraph does not relieve the labeler of its responsibility under paragraph (a) of this section to provide corrected information or an explanation of why the information previously submitted is correct.

§ 830.360 Records to be maintained by the labeler.

(a) Each labeler shall retain, and submit to FDA upon specific request, records showing all unique device identifiers (UDIs) used to identify devices that must bear a UDI on their label, and the particular version or model associated with each device identifier. These records must be retained for 3 years from the date the labeler ceases to market the version or model.

(b) Compliance with this section does not relieve the labeler of the need to comply with recordkeeping requirements of any other FDA regulation.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

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AUTHORITY: 21 U.S.C. 321(h), 353(g), 360c, 360d, 360e, 360i, 360j, 371, 374.

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 860 appear at 73 FR 35341, June 23, 2008, and at 86 FR 54846, Oct. 5, 2021.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by advisory committees, including classification panels, where applicable, in making their recommendations, and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the type of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to advisory committees, including classification panels, or to the Commissioner in connection with classification and reclassification proceedings, will be available to the public.

[43 FR 32993, July 28, 1978, as amended at 86 FR 54846, Oct. 5, 2021]

§ 860.3 Definitions.

For the purposes of this part:

Class means one of the three categories of regulatory control for medical devices, defined as follows:

Class I means the class of devices that are subject only to the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act. A device is in class I if:

(1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or

(2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

Class II means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, which are necessary to provide adequate assurance of safety and effectiveness, and describe how such controls provide such assurance.

Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the Federal Food, Drug, and Cosmetic Act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, or that application of special controls described in the definition of ''*Class II*'' in

this section in addition to general controls, would provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

Classification panel means one of the several advisory committees established by the Commissioner under section 513 of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the Federal Food, Drug, and Cosmetic Act or by the Commissioner.

Classification regulation means a section under parts 862 through 892 of this chapter that contains the identification (general description and intended use) and classification (class I, II or III) of a single device type or more than one related device type(s).

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

De Novo request means any submission under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act for a medical device, requesting classification into class I or class II, including all information submitted with or incorporated by reference therein.

FDA means the Food and Drug Administration.

General controls mean the controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration, listing, and premarket notification), 516 (banned devices), 518 (notification and other remedies), 519 (records, reports, and unique device identification), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.

Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Petition means a submission seeking reclassification of a device in accordance with § 860.123.

Special controls mean the controls necessary to provide reasonable assurance of safety and effectiveness for a generic type of device that is class II. Special controls include performance standards, performance testing, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions, as the Commissioner deems necessary to provide such assurance.

[86 FR 54846, Oct. 5, 2021]

§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

(a) This section governs the availability for public disclosure and the use by the Commissioner of data and information submitted to classification panels or to the Commissioner in connection with the classification or reclassification of devices under this part.

(b) In general, data and information submitted to classification panels in connection with the classification of devices under § 860.84 will be available immediately for public disclosure upon request. However, except as provided by the special rules in paragraph (c) of this section, this provision does not

apply to data and information exempt from public disclosure in accordance with part 20 of this chapter: Such data and information will be available only in accordance with part 20.

(c)(1) Safety and effectiveness data submitted to classification panels or to the Commissioner in connection with the classification of a device under § 860.84, which have not been disclosed previously to the public, as described in § 20.81 of this chapter, shall be regarded as confidential if the device is classified in to class III. Because the classification of a device under § 860.84 may be ascertained only upon publication of a final regulation, all safety and effectiveness data that have not been disclosed previously are not available for public disclosure unless and until the device is classified into class I or II, in which case the procedure in paragraph (c)(2) of this section applies.

(2) Thirty days after publication of a final regulation under § 860.84 classifying a device into class I or class II, safety and effectiveness data submitted for that device that had been regarded as confidential under paragraph (c)(1) of this section will be available for public disclosure and placed on public display in the office of the Dockets Management Staff, Food and Drug Administration unless, within that 30-day period, the person who submitted the data demonstrates that the data still fall within the exemption for trade secrets and confidential commercial information described in § 20.61 of this chapter. Safety and effectiveness data submitted for a device that is classified into class III by regulation in accordance with § 860.84 will remain confidential and unavailable for public disclosure so long as such data have not been disclosed to the public as described in § 20.81 of this chapter.

(3) Because device classification affects generic types of devices, in making determinations under § 860.84 concerning the initial classification of a device, the classification panels and the Commissioner may consider safety and effectiveness data developed for another device in the same generic type, regardless of whether such data are regarded currently as confidential under paragraph (c)(1) of this section.

(d)(1) The fact of its existence and the contents of a petition for reclassification filed in accordance with § 860.130 or § 860.132 are available for public disclosure at the time the petition is received by the Food and Drug Administration.

(2) The fact of the existence of a petition for reclassification filed in accordance with § 860.134 or § 860.136 is available for public disclosure at the time the petition is received by the Food and Drug Administration. The contents of such a petition are not available for public disclosure for the period of time following its receipt (not longer than 30 days) during which the petition is reviewed for any deficiencies preventing the Commissioner from making a decision on it. Once it is determined that the petition contains no deficiencies preventing the Commissioner from making a decision on it, the petition will be filed with the Dockets Management Staff and its entire contents will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. If, during this 30-day period of time, the petition is found to contain deficiencies that prevent the Commissioner from making a decision on it, the petitioner will be so notified and afforded an opportunity to correct the deficiencies.

Thirty days after notice to the petitioner of deficiencies in the petition, the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and

subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the Federal Food, Drug, and Cosmetic Act that falls within the exemption described in §20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in §20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with §860.130 or §860.132, or in a petition submitted in accordance with §860.134 or §860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

(g) Confidentiality of data and information in a De Novo file is as follows:

(1) A ''De Novo file'' includes all data and information from the requester submitted with or incorporated by reference in the De Novo request, any De Novo supplement, or any other related submission relevant to the administrative file, as defined in §10.3(a) of this chapter. Any record in the De Novo file will be available for public disclosure in accordance with the provisions of this section and part 20 of this chapter.

(2) The existence of a De Novo file may not be disclosed by FDA before an order granting the De Novo request is issued unless it previously has been publicly disclosed or acknowledged by the De Novo requester.

(3) Before an order granting the De Novo request is issued, data or information contained in the De Novo file is not available for public disclosure, except to the extent the existence of the De Novo file is disclosable under paragraph (g)(2) of this section and such data or information has been publicly disclosed or acknowledged by the De Novo requester.

(4) After FDA issues an order granting a De Novo request, the data and information in the De Novo file that are not exempt from release under the Freedom of Information Act, 5 U.S.C. 552, are immediately available for public disclosure.

[43 FR 32993, July 28, 1978, as amended at 86 FR 54847, Oct. 5, 2021; 88 FR 45067, July 14, 2023]

§ 860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of special controls for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c)(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety

and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device with questionable safety or effectiveness.

(d)(1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, nonclinical investigations, and analytical studies for in vitro diagnostic devices.

(e)(1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:

(*a*) Provides adequate assurance that the subjects are suitable for the purposes of the study, provides diagnostic criteria of the condition to be treated or diagnosed, provides confirmatory laboratory tests where appropriate and, in the case of a device to prevent a disease or condition, provides evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(*b*) Assigns the subjects to test groups, if used, in such a way as to minimize any possible bias;

(*c*) Assures comparability between test groups and any control groups of pertinent variables such as sex, severity or duration of the disease, and use of therapy other than the test device;

(iii) An explanation of the methods of observation and recording of results utilized, including the variables measured, quantitation, assessment of any subject's response, and steps taken to minimize any possible bias of subjects and observers;

(iv) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be specified and an explanation provided of the methods employed to minimize any possible bias of the observers and analysts of the data. Level and methods of ''blinding,'' if appropriate and used, are to be documented. Generally, four types of comparisons are recognized:

(*a*) *No treatments.* Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients;

(*b*) *Placebo control.* Where there may be a placebo effect with the use of a device, comparison of the results of use of the device with an ineffective device used under conditions designed to resemble the conditions of use under investigation as far as possible;

(*c*) *Active treatment control.* Where an effective regimen of therapy may be used for comparison, e.g., the condition being treated is such that the use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient;

(*d*) *Historical control.* In certain circumstances, such as those involving diseases with high and predictable mortality or signs and symptoms of predictable duration or severity, or in the case of prophylaxis where morbidity is predictable, the results of use of the device may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations who received no treatment or who followed an established effective regimen (therapeutic, diagnostic, prophylactic).

(v) A summary of the methods of analysis and an evaluation of the data derived from the study, including any appropriate statistical methods utilized.

(2) To insure the reliability of the results of an investigation, a well-controlled investigation shall involve the use of a test device that is standardized in its composition or design and performance.

(g)(1) It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and special controls, may support a determination that the device be classified into class III.

(2) The Commissioner may require that a manufacturer, importer, or distributor make reports or provide other information bearing on the classification of a device and indicating whether there is reasonable assurance of the safety and effectiveness of the device or whether it is adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act.

(3) A requirement for a report or other information under this paragraph

will comply with section 519 of the Federal Food, Drug, and Cosmetic Act. Accordingly, the requirement will state the reason or purpose for such request; will describe the required report or information as clearly as possible; will not be imposed on a manufacturer, importer, or distributor of a classified device that has been exempted from such a requirement in accordance with § 860.95; will prescribe the time for compliance with the requirement; and will prescribe the form and manner in which the report or information is to be provided.

(4) Required information that has been submitted previously to the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research, as applicable, need not be resubmitted, but may be incorporated by reference.

[43 FR 32993, July 28, 1978, as amended at 53 FR 11253, Apr. 6, 1988; 73 FR 49942, Aug. 25, 2008; 83 FR 64454, Dec. 17, 2018]

§ 860.10 Implants and life-supporting or life-sustaining devices.

(a) A classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing and an identification of the risks to health, if any, presented by the device. In the case of such a device being recommended for classification or reclassification into class II, the panel shall describe the special controls that, in addition to general controls, the panel believes are necessary to provide reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device. In the case of such a device being classified or reclassified into class II, the Commissioner shall describe the special controls that, in addition to general controls, the panel believes are necessary to provide reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

[83 FR 64455, Dec. 17, 2018]

§ 860.15 Exemptions from sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports) and section 520(f) (good manufacturing practice requirements of the quality system regulation), and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510.

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act the device is to be exempted from or, in the case of a regulation or an order classifying or reclassifying a device into class II, whether the device is to be exempted from the premarket notification requirement under

section 510, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

[83 FR 64455, Dec. 17, 2018]

Subpart B—Classification

§ 860.84 Classification procedures for "preamendments devices."

(a) This subpart sets forth the procedures for the original classification of a generic type of device that was in commercial distribution before May 28, 1976. Such a device will be classified by regulation into either class I (general controls), class II (special controls) or class III (premarket approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§ 860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act because the Food and Drug Administration has determined that the device is not ''substantially equivalent'' to any device subject to this subpart or under section 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act because the device was regarded previously as a new drug. In classifying a *preamendments* device to which this section applies, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7; and

(3) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in § 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device. The recommendation will include:

(1) A summary of the reasons for the recommendation;

(2) A summary of the data upon which the recommendation is based;

(3) An identification of the risks to health (if any) presented by the device;

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice requirements of the quality system regulation) and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510, in accordance with § 860.15;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement, and in the case of classification into class II, a recommendation on the establishment of special controls and whether the device should be exempted from premarket notification in accordance with § 860.15; and

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance

of the safety and effectiveness of the device and an identification of the risks to health, if any, presented by the device, in accordance with § 860.10.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed at Dockets Management Staff upon receipt and are available to the public at *https://www.regulations.gov*.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.95;

(2) If classifying the device into class II, establish the special controls for the device and prescribe whether the premarket notification requirement will apply to the device; and

(3) If classifying an implant, or a life-supporting or life-sustaining device, comply with § 860.10(b).

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 64 FR 404, Jan. 5, 1999; 83 FR 64455, Dec. 17, 2018]

§ 860.90 Consultation with panels.

(a) When the Commissioner is required to consult with a panel concerning a classification under § 860.84, the Commissioner will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members in a telephone or video conference call; or

(2) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

[83 FR 64456, Dec. 17, 2018]

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b) of the Federal Food, Drug, and Cosmetic Act. A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(*l*) of the Federal Food, Drug, and Cosmetic Act. The Commissioner may initiate the reclassification of a device under the following sections of the Federal Food, Drug, and Cosmetic Act:

(1) Section 513(e) (for a classified device other than a device classified into class III under section 513(f)(1) or 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act);

(2) Section 513(f)(3) (for a device classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act); or

(3) Section 520(*l*)(2) (for a device classified into class III under section 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act).

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 83 FR 64456, Dec. 17, 2018]

§ 860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the Federal Food, Drug, and Cosmetic Act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., ''It is requested that __ device(s) be reclassified from class III to a class II'';

(3) A statement of the basis for disagreement with the present classification status of the device;

(4) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(5) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(6) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the Federal Food, Drug, and Cosmetic Act, a summary of the new information;

(7) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition); and

(8) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(b) Each petition submitted pursuant to this section shall be:

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy Staff, 10903 New Hampshire Ave., Bldg. 66, Rm. 5445, Silver Spring, MD 20993–0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Control Room, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, as applicable.

(2) Marked clearly with the section of the Federal Food, Drug, and Cosmetic Act under which the petition is being submitted, *i.e.*, ''513(e),'' ''513(f)(3),'' ''514(b),'' ''515(b),'' or ''520(*l*) Petition'';

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 63 FR 5254, Feb. 2, 1998; 65 FR 17137, Mar. 31, 2000; 73 FR 49942, Aug. 25, 2008; 75 FR 20916, Apr. 22, 2010; 79 FR 77388, Dec. 24, 2014; 82 FR 39535, Aug. 21, 2017; 83 FR 64456, Dec. 17, 2018; 85 FR 18443, Apr. 2, 2020]

§ 860.125 Consultation with panels.

(a) When the Commissioner chooses to refer a reclassification petition to a classification panel for its recommendation under § 860.134(b), or the Commissioner is required to consult with a panel concerning a reclassification petition submitted under § 860.130(d) or received in a proceeding under § 860.133(b), or the Commissioner chooses to consult with a panel with regard to the reclassification of a device initiated by the Commissioner under § 860.134(c) or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, if applicable, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting

panel members and, when possible, nonvoting panel members in a telephone or video conference call; or

(2) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) The Commissioner will consult with a classification panel prior to changing the classification of a device in a proceeding under section 513(e) of the Federal Food, Drug, and Cosmetic Act and § 860.130 upon the Commissioner's own initiative or upon petition of an interested person, and in the latter case, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member.

(d) When a petition is submitted under § 860.134 for a postamendments, not substantially equivalent, device, if the Commissioner chooses to consult with the panel, the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130(d), § 860.136(a), or received in a proceeding under § 860.133(b), the Commissioner may or may not obtain a formal recommendation.

[43 FR 32993, July 28, 1978, as amended at 83 FR 64456, Dec. 17, 2018]

§ 860.130 General procedures under section 513(e) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 513(e) of the Federal Food, Drug, and Cosmetic Act applies to reclassification proceedings under the Federal Food, Drug, and Cosmetic Act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the Federal Food, Drug, and Cosmetic Act (see § 860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with § 860.123.

(c) By administrative order published under this section, the Commissioner may change the classification from:

(1) Class I or class II to class III if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(3) for a class III device; or

(2) Class III or class I to class II if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(2) for a class II device; or

(3) Class III or class II to class I if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(1) for a class I device.

(d)(1) The Commissioner shall consult with a classification panel and may secure a recommendation with respect to reclassification of a device from a classification panel. The panel will consider reclassification in accordance with the consultation procedures of § 860.125. A recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner publishes an administrative order under this section.

(2) The Commissioner may change the classification of a device by administrative order published in the FEDERAL REGISTER following publication of a proposed reclassification order in the FEDERAL REGISTER, a meeting of a device classification panel described in section 513(b) of the Federal Food, Drug, and Cosmetic Act, and consideration of comments to a public docket.

(e) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner will either deny the petition by order published in the FEDERAL REGISTER or give notice of the intent to initiate a change in the classification of the device.

(f) If a device is reclassified under this section, the administrative order effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) An administrative order under this section changing the classification of a device to class II may provide that such reclassification will not take effect until the effective date of a performance standard for the device established under section 514 of the Federal Food, Drug, and Cosmetic Act or other special controls established under the order. An order under this section changing the classification of a device to class II may also establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 83 FR 64456, Dec. 17, 2018]

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the Federal Food, Drug, and Cosmetic Act.

(a) Sections 514(b) and 515(b) of the Federal Food, Drug, and Cosmetic Act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to petition to change the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding to develop a performance standard for the device if in class II or to issue an order requiring premarket approval for the device if in class III.

(b) If the Commissioner agrees that the new information submitted in response to a proposed order to require premarket approval of a device issued under section 515(b) of the Federal Food, Drug, and Cosmetic Act warrants a change in classification, the Commissioner shall follow the administrative order procedures under section 513(e) of the Federal Food, Drug, and Cosmetic Act and § 860.130 to effect such a change.

(c) If the Commissioner does not agree that the new information submitted in response to a proposed order to require premarket approval of a device issued under section 515(b) of the Federal Food, Drug, and Cosmetic Act warrants a change in classification, the Commissioner will deny the petition.

(d) The procedures under section 514(b) of the Federal Food, Drug, and Cosmetic Act are as follows:

(1) Within 30 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner either denies the petition or gives notice of the intent to initiate a change in classification in accordance with § 860.130.

[43 FR 32993, July 28, 1978, as amended at 83 FR 64457, Dec. 17, 2018]

§ 860.133 Procedures when the Commissioner initiates a proceeding to require premarket approval under section 515(b) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 515(b) of the Federal Food, Drug, and Cosmetic Act applies to proceedings to require premarket approval for a class III preamendments device.

(b) The Commissioner may require premarket approval for a class III preamendments device by administrative order published in the FEDERAL REGISTER following publication of a proposed order in the FEDERAL REGISTER, a meeting of a device classification panel described in section 513(b) of the Federal Food, Drug, and Cosmetic Act, and consideration of comments from all affected stakeholders, including patients, payors, and providers. The panel will consider reclassification petitions received in the proceeding in accordance with section 513(e) of the Federal Food, Drug, and Cosmetic and the applicable consultation procedures in § 860.125. A recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner publishes an administrative order under this section.

[83 FR 64457, Dec. 17, 2018]

§ 860.134 Procedures for reclassification of "postamendments devices" under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act applies to proceedings for reclassification of a device currently in class III by operation of section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:

(1) It is substantially equivalent to another device that was in commercial distribution before that date and had not been regulated before that date as a new drug; or

(2) It is substantially equivalent to another device that was not in commercial distribution before such date but which has been classified into class I or class II; or

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section; or

(4) The device is classified under a request for De Novo classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act.

(b) The procedures for effecting reclassification under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act when initiated by a manufacturer or importer are as follows:

(1) The manufacturer or importer of the device petitions for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner may for good cause shown refer the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in § 860.84(c) for the original classification of a ''preamendments device'', the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed at Dockets Management Staff upon receipt and are available to the public and posted at *https://www.regulations.gov*.

(5) The panel recommendation is published in the FEDERAL REGISTER as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.10, relating to the classification of implants and life-supporting or life-sustaining devices, and § 860.15, relating to exemptions from certain requirements of the Federal Food, Drug, and Cosmetic Act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

(c) By administrative order published under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 513(f)(1) either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is

sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the FEDERAL REGISTER seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the FEDERAL REGISTER.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 73 FR 34860, June 19, 2008; 83 FR 64457, Dec. 17, 2018]

§ 860.136 Procedures for transitional products under section 520(l) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 520(*l*)(2) of the Federal Food, Drug, and Cosmetic Act applies to reclassification proceedings initiated by the Commissioner or in response to a request by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(*l*)(1). This section applies only to devices that the Food and Drug Administration regarded as ''new drugs'' before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act when initiated by a manufacturer or importer are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(4) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(5) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

(c) By administrative order, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the FEDERAL REGISTER seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification

panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the FEDERAL REGISTER.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

[43 FR 32993, July 28, 1978, as amended at 83 FR 64458, Dec. 17, 2018]

Subpart D—De Novo Classification

SOURCE: 86 FR 54847, Oct. 5, 2021, unless otherwise noted.

§ 860.200 Purpose and applicability.

(a) The purpose of this part is to establish an efficient, transparent, and thorough process to facilitate De Novo classification into class I or class II for devices for which there is no legally marketed device on which to base a review of substantial equivalence and which meet the definition of class I or class II as described in section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3.

(b) De Novo requests can be submitted for a single device type:

(1) After receiving a not substantially equivalent determination in response to a premarket notification (510(k)), or

(2) If a person determines there is no legally marketed device upon which to base a determination of substantial equivalence.

§ 860.210 De Novo request format.

(a) Each De Novo request or information related to a De Novo request pursuant to this part must be formatted in accordance with this section. Each De Novo request must be provided as a single version in electronic format. These materials must:

(1)(i) For devices regulated by the Center for Devices and Radiological Health, be sent to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress*.

(ii) For devices regulated by the Center for Biologics Evaluation and Research, be sent to the current address displayed on the website *https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper*.

(2) Be signed by the requester or an authorized representative.

(3) Be designated ''De Novo Request'' in the cover letter.

(4) Have all content used to support the request written in, or translated into, English.

§ 860.220 De Novo request content.

(a) Unless the requester justifies an omission in accordance with paragraph (c) of this section, a De Novo request must include:

(1) *Table of contents.* A table of contents that specifies the volume (if the De Novo request contains more than one volume) and page number for each item.

(2) *Administrative information.* The name, address, phone, and email address of the requester and U.S. representative, if applicable. The establishment registration number, if applicable, of the owner or operator submitting the De Novo request.

(3) *Regulatory history.* Identify any prior submissions to FDA for the device, including, but not limited to, any premarket notifications (510(k)s) submitted under part 807 of this chapter; applications for premarket approval (PMAs) submitted under part 814 of this chapter; applications for humanitarian device exemption (HDE) submitted under part 814 of this chapter; applications for investigational device exemption (IDEs) submitted under part 812 of this chapter; requests for designation (RFD) under § 3.7 of this chapter; requests for information under section 513(g) of the Federal Food, Drug, and Cosmetic Act; applications for emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act; pre-submissions, or previously submitted De Novo

requests; or state that there have been no prior submissions.

(4) *Device name.* The generic name of the device as well as any proprietary name or trade name.

(5) *Indications for use.* A general description of the disease or condition the device is intended to diagnose, treat, prevent, cure or mitigate, or affect the structure or function of the body, including a description of the patient population for which the device is intended. The indications for use include all the labeled patient uses of the device, including if it is prescription or over-the-counter.

(6) *Device description.* A complete description of:

(i) The device, including, where applicable, pictorial representations, device specifications, and engineering drawings;

(ii) Each of the functional components or ingredients of the device, if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition and/or the effect of the device on the structure or function of the body;

(iv) The principles of operation of the device; and

(v) The relevant FDA assigned reference number(s) for any medical devices (such as accessories or components) that are intended to be used with the device and that are already legally marketed.

(7) *Alternative practices and procedures.* A description of existing alternative practices or procedures that are used in diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended or which similarly affect the structure or function of the body and that are known or should reasonably be known to the requester.

(8) *Classification summary.* (i) For devices not the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, a complete description of:

(A) The searches used to establish that no legally marketed device of the same type exists.

(B) A list of classification regulations, PMAs, HDEs, premarket notifications (510(k)s), EUAs, and/or product codes regarding devices that are potentially similar to the subject device.

(C) A rationale explaining how the device that is the subject of the De Novo request is different from the devices covered by the classification regulations, PMAs, HDEs, 510(k)s, EUAs, and/or product codes identified in paragraph (a)(8)(i)(B) of this section.

(ii) For devices which were the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act that were determined not substantially equivalent (NSE), the relevant 510(k) number, along with a summary of the search performed to confirm the device has not been classified or reclassified since the date the NSE order was issued by FDA pursuant to §807.100(a) of this chapter.

(9) *Summary of risks and mitigations.* A summary of probable risks to health associated with use of the device that are known or should reasonably be known to the requester and the proposed mitigations, including general controls and, if the classification recommendation from paragraph (a)(11) of this section is class II, special controls for each risk. For each mitigation measure that involves specific performance testing or labeling, the De Novo request must provide a reference to the associated section or pages for the supporting information in the De Novo request.

(10) *Proposed special controls.* If the classification recommendation from paragraph (a)(11) of this section is class II, then the summary must include an initial draft proposal for applicable special controls and a description of how those special controls provide reasonable assurance of safety and effectiveness.

(11) *Classification recommendation.* The recommended class (I or II) must be identified and must be supported by a description of why general controls, or general and special controls, are adequate to provide reasonable assurance of safety and effectiveness.

(12) *Standards.* Reference to any published voluntary consensus standards that are relevant to any aspect of the

safety or effectiveness of the device and that are known or should reasonably be known to the requester. Such standards include voluntary consensus standards whether recognized or not yet recognized under section 514(c) of the Federal Food, Drug, and Cosmetic Act. Provide adequate information to demonstrate how the device meets, or justify any deviation from, the referenced standard.

(13) *Summary of studies.* An abstract of any information or report described in the De Novo request under paragraph (a)(16)(ii) of this section and a summary of the results of technical data submitted under paragraph (a)(15) of this section. Each such study summary must include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section must also include the following:

(i) A summary of each nonclinical study submitted in the De Novo request;

(ii) A summary of each clinical investigation involving human subjects submitted in the De Novo request, including a discussion of investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, subject discontinuation, subject complaints, device failures (including unexpected software events, if applicable) and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate. Any investigation conducted under an investigational device exemption (IDE) under part 812 of this chapter must be identified as such.

(14) *Benefit and risk considerations.* A discussion demonstrating that:

(i) The data and information in the De Novo request constitute valid scientific evidence within the meaning of § 860.7(c) and

(ii) Pursuant to § 860.7, when subject to general controls, or general and special controls, the probable benefit to health from use of the device outweighs any probable injury or illness from such use.

(15) *Technical sections.* The following technical sections, which must contain data and information in sufficient detail to permit FDA to determine whether to grant or decline the De Novo request:

(i) A section containing the results of the nonclinical studies of the device, including, as appropriate, microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, electrical safety, electromagnetic compatibility, and other laboratory or animal tests. Information on nonclinical studies must include protocols and complete test reports for each study. For those nonclinical studies subject to part 58 of this chapter, this section must include a statement that each such study was conducted in compliance with such regulations, or, if the study was not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(ii) For all devices that incorporate software, a section containing all relevant software information and testing, including, but not limited to, appropriate device hazard analysis, hardware, and system information.

(iii) A section containing results of each clinical investigation of the device involving human subjects, including clinical protocols, number of investigators and subjects per investigator, investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, subject discontinuation, subject complaints, device failures (including unexpected software events if applicable) and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the results of the clinical investigations, contraindications, warnings, precautions, and other limiting statements relevant to the use of the device

type, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE under part 812 of this chapter must be identified as such. Information on clinical investigations involving human subjects must include the following:

(A) For clinical investigations conducted in the United States, a statement with respect to each investigation that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under §56.104 or §56.105 of this chapter, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter; or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(B) For clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with part 812 of this chapter concerning sponsors of clinical investigations and clinical investigators, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(C) For clinical investigations conducted outside the United States that are intended to support the De Novo request, the requirements under §812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in §812.28(a) of this chapter, include either a waiver request in accordance with §812.28(c) of this chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(D) A statement that each investigation has been completed per the protocol or a summary of any protocol deviations.

(E) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(F) For a De Novo request that relies primarily on data from a single investigator at one investigation site, a justification showing that these data and other information are sufficient to reasonably demonstrate the safety and effectiveness of the device when subject to general controls or general and special controls, and to ensure that the results from a site are applicable to the intended population.

(G) A discussion of how the investigation data represent clinically significant results, pursuant to §860.7(e).

(16) *Other information*. (i) A bibliography of all published reports not submitted under paragraph (a)(15) of this section, whether adverse or supportive, known to or that should reasonably be known to the requester and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the requester from any source, foreign or domestic, including information derived from investigations other than those in the request and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the requester, if requested by FDA.

(17) *Samples*. If requested by FDA, one or more samples of the device and its components. If it is impractical to submit a requested sample of the device, the requester must name the location at which FDA may examine and test one or more of the devices.

(18) *Labeling and advertisements*. Labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its

use. Where applicable, photographs or engineering drawings must be supplied.

(19) *Other information*. Such other information as is necessary to determine whether general controls or general and special controls provide reasonable assurance of safety and effectiveness of the device.

(b) Pertinent information in FDA files specifically referred to by a requester may be incorporated into a De Novo request by reference. Information submitted to FDA by a person other than the requester will not be considered part of a De Novo request unless such reference is authorized in writing by the person who submitted the information.

(c) If the requester believes that certain information required under paragraph (a) of this section to be in a De Novo request is not applicable to the device that is the subject of the De Novo request, and omits any such information from the De Novo request, the requester must submit a statement that specifies the omitted information and justifies the omission. The statement must be submitted as a separate section in the De Novo request and listed in the table of contents. If the justification for the omission is not accepted by FDA, FDA will so notify the requester.

(d) The requester must update the pending De Novo request with new safety and effectiveness information learned about the device from ongoing or completed studies and investigations that may reasonably affect an evaluation of the safety or effectiveness of the device as such information becomes available.

§ 860.230 Accepting a De Novo request.

(a) The acceptance of a De Novo request means that FDA has made a threshold determination that the De Novo request contains the information necessary to permit a substantive review. Within 15 days after a De Novo request is received by FDA, FDA will notify the requester whether the De Novo request has been accepted.

(b) If FDA does not find that any of the reasons in paragraph (c)(1) of this section for refusing to accept the De Novo request apply or FDA fails to complete the acceptance review within 15 days, FDA will accept the De Novo request for review and will notify the requester. The notice will include the De Novo request reference number and the date FDA accepted the De Novo request. The date of acceptance is the date that an accepted De Novo request was received by FDA.

(c)(1) FDA may refuse to accept a De Novo request if any of the following applies:

(i) The requester has an open or pending premarket submission or reclassification petition for the device;

(ii) The De Novo request is incomplete because it does not on its face contain all the information required under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act or does not contain each of the items required under this part, or a justification for omission of any item;

(iii) The De Novo request is not formatted as required under § 860.210;

(iv) The De Novo request is for multiple devices and those devices are of more than one type; or

(v) The requester has not responded to, or has failed to provide a rationale for not responding to, deficiencies identified by FDA in previous submissions for the same device, including those submissions described in § 860.220(a)(3).

(2) If FDA refuses to accept a De Novo request, FDA will notify the requester of the reasons for the refusal. The notice will identify the deficiencies in the De Novo request that prevent accepting and will include the De Novo request reference number.

(3) If FDA refuses to accept a De Novo request, the requester may submit the additional information necessary to comply with the requirements of section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act and this part. The additional information must include the De Novo request reference number of the original submission. If the De Novo request is subsequently accepted, the date of acceptance is the date FDA receives the additional information.

§ 860.240 Procedures for review of a De Novo request.

(a) FDA will begin substantive review of a De Novo request after the De Novo request is accepted under § 860.230.

Within 120 days after receipt of a De Novo request or receipt of additional information that results in the De Novo request being accepted under § 860.230, FDA will review the De Novo request and send the requester an order granting the De Novo request under § 860.260(a) or an order declining the De Novo request under 860.260(b).

(b) A requester may supplement or amend a pending De Novo request to revise existing information or provide additional information.

(1) FDA may require additional information regarding the device that is necessary for FDA to complete the review of the De Novo request.

(2) Additional information submitted to FDA must include the reference number assigned to the original De Novo request and, if submitted on the requester's own initiative, the reason for submitting the additional information.

(c) Prior to granting or declining a De Novo request, FDA may inspect relevant facilities to help determine:

(1) That clinical or nonclinical data were collected in a manner that ensures that the data accurately represents the benefits and risks of the device; or

(2) That implementation of Quality System Regulation (part 820 of this chapter) requirements, in addition to other general controls and any specified special controls, provide adequate assurance that critical and/or novel manufacturing processes produce devices that meet specifications necessary to ensure reasonable assurance of safety and effectiveness.

§ 860.250 Withdrawal of a De Novo request.

(a) FDA considers a De Novo request to have been withdrawn if:

(1) The requester fails to provide a complete response to a request for additional information pursuant to § 860.240(b)(1) within 180 days after the date FDA issues such request;

(2) The requester fails to provide a complete response to the deficiencies identified by FDA pursuant to § 860.230(c)(2) within 180 days of the date notification was issued by FDA;

(3) The requester does not permit an authorized FDA employee an opportunity to inspect the facilities, pursuant to § 860.240(c), at a reasonable time and in a reasonable manner, and to have access to copy and verify all records pertinent to the De Novo request; or

(4) The requester submits a written notice to FDA that the De Novo request has been withdrawn.

(b) If a De Novo request is withdrawn, the Agency will notify the requester. The notice will include the De Novo request reference number and the date FDA considered the De Novo request withdrawn.

§ 860.260 Granting or declining a De Novo request.

(a)(1) FDA will issue to the requester an order granting a De Novo request if none of the reasons in paragraph (c) of this section for declining the De Novo request applies.

(2) If FDA grants a De Novo request, within 30 days after the issuance of an order granting the De Novo request, FDA will publish in the FEDERAL REGISTER a notice of the classification order, including any special controls.

(b) If FDA declines a De Novo request, FDA will issue a written order to the requester.

(c) FDA may decline a De Novo request if the requester fails to follow the requirements of this part or if, upon the basis of the information submitted in the De Novo request or any other information before FDA, FDA determines:

(1) The device does not meet the criteria under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3 for classification into class I or II;

(2) The De Novo request contains a false statement of material fact or there is a material omission;

(3) The device's labeling does not comply with the requirements in parts 801 and 809 of this chapter, as applicable;

(4) The product described in the De Novo request does not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act and is not a combination product as defined at § 3.2(e) of this chapter;

(5) The device is of a type which has already been approved in existing applications for premarket approval (PMAs) submitted under part 814 of this chapter;

(6) The device is of a type that has already been classified into class I, class II, or class III;

(7) An inspection of a relevant facility under § 860.240(c) results in a determination that general or general and special controls would not provide reasonable assurance of safety and effectiveness;

(8) A nonclinical study subject to part 58 of this chapter that is described in the De Novo request, and that is essential to show there is reasonable assurance of safety, was not conducted in compliance with part 58 of this chapter and no reason for the noncompliance is provided or, if a reason is provided, the practices used in conducting the study do not support the validity of the study;

(9) A clinical investigation described in the De Novo request involving human subjects that is subject to the institutional review board regulations in part 56 of this chapter, informed consent regulations in part 50 of this chapter, or GCP described in § 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable;

(10) A clinical or nonclinical study necessary to demonstrate that general controls or general and special controls provide reasonable assurance of safety and effectiveness:

(i) Has not been completed per the study protocol, or

(ii) Deficiencies related to the investigation and identified in any request for additional information under § 860.240(b)(1) have not been adequately addressed; or

(11) After a De Novo request is accepted for review under § 860.230(b), the requester makes significant unsolicited changes to the device's:

(i) Indications for use; or

(ii) Technological characteristics.

(d) An order declining a De Novo request will inform the requester of the deficiencies in the De Novo request, including each applicable ground for declining the De Novo request.

(e) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to grant or decline a De Novo request. FDA may use information other than that submitted by the requester in making such determination.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

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AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 45 FR 7484, Feb. 1, 1980, unless otherwise noted.

Subpart A—General

§ 861.1 Purpose and scope.

(a) This part implements section 514 of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) The Food and Drug Administration may determine that a performance standard, as described under special controls for class II devices in § 860.7(b) of this chapter, is necessary to provide reasonable assurance of the safety and effectiveness of the device. Performance standards may be established for:

(1) A class II device;

(2) A class III device which, upon the effective date of the standard, is reclassified into class II; and