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Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA developed this document to provide guidance to industry and FDA staff about best practices in selecting a predicate device for premarket notification [510(k)] submissions. Specifically, this guidance recommends four (4) best practices to employ when selecting a predicate device used to support a 510(k) submission. The recommendations provided in this guidance are not intended to propose any changes to applicable statutory and regulatory standards, such as how FDA evaluates substantial equivalence, or the applicable requirements, including the requirement for valid scientific evidence. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process. This guidance and associated recommendations are consistent with and are intended to be used in conjunction with the FDA guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"[1] (hereinafter, 510(k) Program Guidance) and other relevant FDA guidances on 510(k) submissions.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

II. Background

A. The 510(k) Process

The framework under which FDA regulates medical devices was put into place when Congress enacted the Medical Device Amendments (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) on May 28, 1976. Under section 510(k) of the FD&C Act, a manufacturer must submit a premarket notification (often referred to as a 510(k)) to FDA at least 90 days before introducing, or delivering for introduction, a device into interstate commerce for commercial distribution so the Agency can determine whether or not the device meets the criteria for market clearance (sections 510(k), 510(n), and 513(i) of the FD&C Act). A 510(k) is required for devices intended for human use, for which a premarket approval application (PMA) is not required, unless the device is exempt from the 510(k) requirements of the FD&C Act and does not exceed the relevant limitations of exemptions in the device classification regulations.

A 510(k) is a marketing submission made by a manufacturer to FDA to demonstrate that the device to be marketed is substantially equivalent to a "predicate device" (section 513(i) of the FD&C Act and 21 CFR 807.92(a)(3)-(6)). Substantial equivalence is rooted in a comparison between the "new device"[2] and predicate device(s).[3]

The Agency bases its decision on whether the device is substantially equivalent (SE) to a predicate device using the statutory criteria in section 513(i) of the FD&C Act. For FDA to find a new device SE to a predicate device, FDA must first find that the new device and predicate device have the same intended use. FDA must then find that the new device and predicate device have the same technological characteristics, or if they do not, that the different technological characteristics[4] of the new device do not raise different questions of safety and effectiveness and that the new device is as safe and effective as a predicate device. FDA conducts this evaluation by reviewing the proposed scientific methods for evaluating new/different technological characteristics' effects on safety and effectiveness and accompanying performance data to determine whether the methods are acceptable and whether the data demonstrates SE. A new device requiring premarket notification cannot be introduced into interstate commerce for

[2] For purposes of this guidance, a "new device" means a device within the meaning of section 201(h) of the FD&C Act that is not legally marketed. It can be either a completely new device (i.e., one that has not received FDA's marketing authorization) or a modification of a legally marketed device that would require a new 510(k).

[3] A predicate device is a legally marketed device. Under 21 CFR 807.92(a)(3), a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I, or a device which has been found to be substantially equivalent through the 510(k) premarket notification process. Moreover, "[a] device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of [FDA] or that has been determined to be misbranded or adulterated by a judicial officer." Section 513(i)(2) of the FD&C Act.

[4] For purposes of an SE determination, "'different technological characteristics' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device." Section 513(i)(1)(B) of the FD&C Act.

commercial distribution until FDA issues an order stating that the device has been determined to be SE (section 513(f)(1) of the FD&C Act).[5]

B. 510(k) Modernization

In April 2018, CDRH issued the Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health[6] (herein referred to as the "Safety Action Plan") to communicate CDRH's vision for modernizing measures to improve the safety of medical devices while continuing to create more efficient pathways to bring critical devices to patients. The Safety Action Plan describes the efforts underway to modernize the 510(k) program.

In November 2018, FDA announced transformative new steps to modernize FDA's 510(k) program to advance the review of the safety and effectiveness of medical devices. In connection with this announcement, FDA also requested public feedback on these steps to continue to modernize the framework for 510(k) review while promoting innovation and improving safety by driving innovators toward reliance on more modern predicate devices or objective performance criteria when they seek to bring new devices to the market and ultimately to patients. FDA indicated that it is looking at ways to promote the use of more recent predicates because it believes that newer devices should be compared to the benefits and risks of more modern technology.

To advance these goals, FDA discussed several potential options for 510(k) modernization. The statement discussed that the Agency considered making public on its website those cleared devices that demonstrated substantial equivalence to older predicate devices. FDA also considered focusing on predicates that were more than ten (10) years old as a starting point, so the public was made aware of those technologies. FDA's goal in focusing on older predicates was to encourage manufacturers to continually offer patients devices with the latest improvements and advances. FDA issued a public notice on January 22, 2019[7] on FDA's website that requested public comment on this proposal.

FDA reviewed all comments submitted to the docket and acknowledges that the initial proposal of focusing only on older predicates may not optimally promote safer and more effective devices. For example, if selecting a predicate for an implant, older devices may potentially have long-term safety and effectiveness data that establishes a history of safe and effective use. Conversely, when selecting a predicate for a device that includes software, a more recently

[5] Under section 510(k) of the FD&C Act, premarket notification is required for devices that are not subject to a premarket approval application, unless the device is exempt from the 510(k) requirements of the FD&C Act and does not exceed the limitations of exemptions for each of the device classification regulations (e.g., 21 CFR Parts 862-892).

[6] Available at https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health.

[7] Available at https://wayback.archive-it.org/7993/20190206202131/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm. Public comments submitted can be searched under the docket FDA-2018-N-4751, available at https://www.regulations.gov/docket/FDA-2018-N-4751/comments.

cleared device could include modern safety features due to rapid technological advances that affect cybersecurity, interoperability, and modern software architectures.

After considering the docket comments, FDA believes that it may be more appropriate to modernize the 510(k) process with respect to the use of predicate devices by focusing on utilizing best practices when selecting a predicate device rather than just their age. Therefore, FDA is issuing this draft guidance to propose ways to encourage the use of best practices when selecting a predicate device.

FDA developed this draft guidance to propose factors for consideration as best practices for choosing a predicate device. These best practices include consideration of the characteristics of predicate devices rather than focusing on the age of the predicate. FDA believes that this will encourage the evolution of safer and more effective medical devices in the 510(k) program over time. Additionally, FDA believes that identification of the characteristics of predicate devices used to support a 510(k) submission in the accompanying 510(k) Summary may provide additional transparency to the public for devices subject to 510(k) requirements.[8]

III. Scope

This guidance provides recommendations to industry and FDA staff about the best practices of choosing a predicate device for a 510(k) submission. This guidance is intended to be used in conjunction with the 510(k) Program Guidance.[9] The recommendations provided in this guidance are not intended to propose any changes to applicable statutory and regulatory standards, such as how FDA evaluates substantial equivalence, or the applicable requirements, including the requirement for valid scientific evidence. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process.

This guidance is also not intended to supplant existing device-specific guidance but may cover broader areas not addressed in device-specific guidances.

IV. How to use this guidance

This guidance is intended to guide submitters through the best practices in selecting a predicate device for a 510(k) submission. This guidance is intended to be used while a submitter is preparing their 510(k) submission to assist with the identification of potential predicate device(s) to support their device's substantial equivalence to a legally marketed device. Based on FDA's experience in reviewing 510(k) submissions, the Agency is aware that many submitters include

[8] Consistent with the 510(k) Program Guidance and as specified in 21 CFR 807.92(a)(6), the 510(k) Summary shall contain the following information: "If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in [21 CFR 807.92(a)(3)], a summary of the technological characteristics of the subject device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in [21 CFR 807.92(a)(3)]."

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

in their 510(k) submission a completed 510(k) flowchart with a discussion describing why the submitter believes their device is substantially equivalent to the predicate device.[10]

When considering the selection of predicate devices during 510(k) submission preparation, submitters should consider the list of legally marketed devices that they believe have the same intended use as the subject device and when any differences in technological characteristics do not raise different questions about safety and effectiveness, hereafter referred to as a "valid predicate device."[11, 12] FDA recommends narrowing this list of valid predicate device(s) to the predicate device[13] identified by the submitter to support the 510(k) submission using the best practices outlined in Section V of this guidance, in conjunction with the 510(k) Program Guidance.[14] A visual representation of this concept is illustrated in Figure 1 below.

[10] For example, FDA has guidance on the "Format for Traditional and Abbreviated 510(k)s," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks. Submitters could include such an assessment in Section 12 (Substantial Equivalence Discussion) of their 510(k) submission.

[11] Consistent with sections 510(k), 510(n), and 513(i) of the FD&C Act and the 510(k) Program Guidance, while submitters propose a predicate device in their 510(k) submission, FDA determines whether a subject and predicate device are substantially equivalent. This determination includes whether a valid predicate device exists for the subject device.

[12] Consistent with the 510(k) Program Guidance, if FDA has established special controls applicable to the device type, the 510(k) would also need to demonstrate that the proposed device meets the relevant special controls for the device to be classified into class II.

[13] Consistent with the 510(k) Program Guidance, a submitter may use multiple predicate devices to help demonstrate substantial equivalence in certain circumstances. Submitters sometimes choose to do this when combining features from two or more predicate devices with the same intended use into a single new device, when seeking to market a device with more than one intended use, or when seeking more than one indication for use under the same intended use. Additionally, while FDA does not consider reference devices to be predicate devices, reference devices can be used to support a 510(k) submission beyond Decision 4 in the 510(k) flowchart (See Appendix A in the 510(k) Program Guidance). For example, reference devices can be used to support scientific methodology or standard reference values at Decision 5a in the 510(k) flowchart.

[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

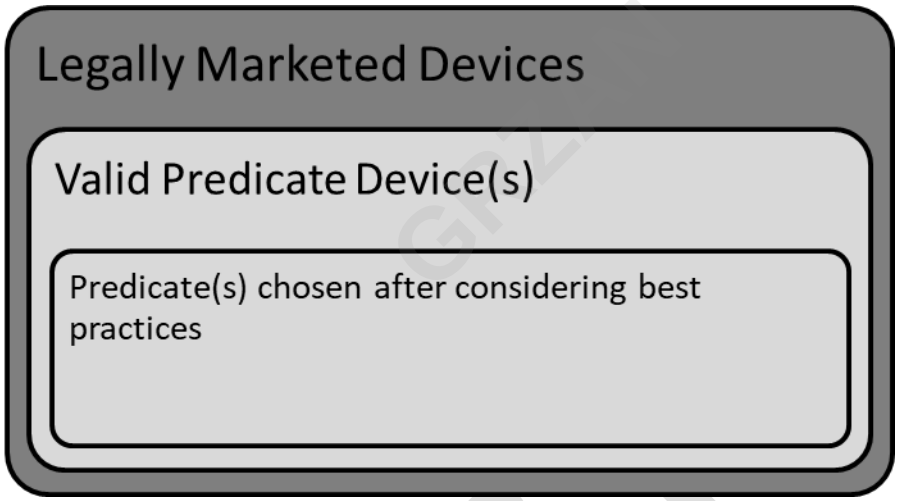


Figure 1. Visual depiction of the relevant terminology used in this guidance.

FDA recommends the submitter include within their 510(k) submission how they used the best practices identified in this guidance in selecting the predicate device(s) used to support the 510(k) submission. For example, if a valid predicate device consistent with the best practices identified in this guidance is not available, FDA recommends describing in the 510(k) submission how any known concerns with the valid predicate device have been mitigated with the subject device (e.g., design features, performance testing). FDA also recommends that the submitter summarize how the best practices were utilized in the selection of the predicate device used to support the 510(k) submission in the 510(k) Summary (See Section VI of this guidance). These recommendations are intended to aid the submitter in selecting a predicate for their device and help provide additional transparency to the public in the 510(k) summary if the 510(k) submission is cleared by FDA.

V. Best practices for selecting a predicate device

FDA identifies all devices cleared through the 510(k) process in the publicly available FDA 510(k) Premarket Notification Database.[15] This online database is updated monthly by FDA. Most submitters likely start with basic administrative information to identify valid predicate device(s), including but not limited to the:

- Trade names of similar devices;
- Manufacturer(s) of similar devices;
- 510(k) numbers for similar devices; and
- Searching of classification information (e.g., product codes, classification regulation) for similar devices.

[15] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

Once legally marketed devices have been identified, FDA recommends reviewing the publicly-available 510(k) Summary[16] and Indications for Use documents for each device being considered by the submitter as a valid predicate device. In addition to these basic administrative items, FDA recommends submitters apply the best practices identified below when selecting a predicate device to support the 510(k) submission.

A. Predicate devices cleared using well-established methods

FDA recommends selecting a valid predicate device that was cleared using well-established methods.[17] These methods include those from a currently FDA-recognized voluntary consensus standard,[18] an FDA guidance document,[19] a qualified medical device development tool (MDDT),[20] or a widely available and accepted method published in the public domain or scientific literature for the context of use, or found acceptable through the submitter's own previous premarket submission. FDA recommends prioritizing predicate devices with methods developed within a consensus environment, and those subject to public comment or peer review. FDA believes that when selecting a valid predicate device, submitters should consider how much information is available regarding the test method(s) used in support of the predicate device's 510(k) clearance and whether those methods continue to be appropriate for evaluating the subject device. For example, voluntary consensus standards periodically undergo revisions and the methods used to evaluate devices can change with both industry and FDA experience with a device.

Once the submitter has identified a list of valid predicate devices, FDA recommends conducting a search of the nonclinical tests submitted, referenced, or relied on in the 510(k) submission[21] to support a determination of substantial equivalence. For example, when selecting between two similar valid predicate devices, where one identified performing testing using FDA guidance and

[16] As specified in 21 CFR 807.87(h), a 510(k) Statement as described in 21 CFR 807.93 may be provided by the submitter in lieu of a 510(k) Summary. However, in order to facilitate transparency, FDA encourages all submitters to utilize the 510(k) Summary option.

[17] FDA acknowledges this information may not always be publicly available for a predicate device, especially for those that were not recently cleared.

[18] For the current edition of FDA-recognized standard(s), see the Recognized Consensus Standards Database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

[19] A list of FDA guidance documents is available on FDA's website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[20] A list of qualified MDDTs is available on FDA's website at https://www.fda.gov/medical-devices/medical-device-development-tools-mddt.

[21] In accordance with 21 CFR 807.92(a)(3), the 510(k) Summary must identify the predicate relied upon for a substantial equivalence determination. In accordance with 21 CFR 807.92, FDA describes the requirements and recommendations of the content to be included in a 510(k) Summary in Appendices B and C of the 510(k) Program Guidance. 510(k) Summaries for devices that have been cleared for marketing through the FDA can be found in the 510(k) Premarket Notification Database on the FDA website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

FDA recognized voluntary consensus standards while the other did not, FDA recommends the submitter select the valid predicate device in which testing relied on these well-established methods. FDA considers it a best practice to select a predicate that was cleared using well-established methods, as this will continue to advance the 510(k) Program, by encouraging the evolution of safer and more effective medical devices in the 510(k) program over time, and ensure that the subject device is evaluated using updated scientific methods whenever possible.

B. Predicate devices meet or exceed expected safety and performance

FDA considers it a best practice to select a valid predicate device that continues to perform safely and as intended by the manufacturer during use in its intended environment of use whenever possible. FDA recommends selecting a valid predicate device after considering how any reported medical device-related adverse events, malfunctions, or deaths may have a role in the safety and effectiveness of the device. New information about a device's safety and/or effectiveness, including unanticipated adverse events, may become available once the device is more widely distributed and used commercially. Also, subsequent changes made to the device, including material changes, or its manufacturing process may lead to unanticipated effects that cannot be comprehensively captured during premarket review.[22] This new information may include, but is not limited to, a newly recognized type of adverse event associated with a medical device, an increase in the severity or frequency of a known adverse event, new product-product interactions, or device malfunctions.

Once the submitter has identified a list of valid predicate devices, FDA recommends conducting a search for any reported injury, deaths, or malfunctions using the following FDA databases:

- Manufacturer and User Facility Device Experience (MAUDE) Database;[23]
- Medical Device Reporting (MDR) Database;[24] and
- MedSun Reports Database.[25]

FDA recommends searching each of the above databases for any reports of unexpected injury, deaths, or malfunctions associated with the available valid predicate devices. For example, when selecting a predicate device for an infusion pump, if the database search reveals a high frequency of reports of battery failures related to the predicate device that resulted in serious injuries to the operator, such events could suggest fundamental design issues with this valid predicate device and FDA recommends selection of a different valid predicate device for the 510(k) submission

[22] The regulatory criteria for when a premarket notification submission is required for a change to an existing device are outlined in 21 CFR 807.81(a)(3). For more information regarding when a premarket modification submission is required refer to the FDA guidance titled, "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device, and the FDA guidance titled, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

[23] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

[24] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.cfm.

[25] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchreporttext.cfm.

whenever possible. If another valid predicate device is not available, FDA recommends that the submitter describe in the 510(k) submission how the subject device mitigates the known concerns with the predicate device used to support the 510(k) submission.

C. Predicate devices without unmitigated use-related or design-related safety issues

FDA recommends selecting a valid predicate device that does not have unmitigated use-related or design-related safety issues, including consideration of emerging signals or safety communications.[26] New information about a device's safety and/or effectiveness can become available once the device is more widely distributed and used. This new information could represent a signal and may include information related to device malfunctions or patient injuries potentially related to improper device use or design.

Consistent with the FDA guidance "Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals")," [27] an emerging signal is new information about a device that supports a new causal association or a new aspect of a known association between a device and an adverse event or set of adverse events and for which FDA has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions and/or the known benefit-risk profile of the device. An emerging signal may be associated with one product from one manufacturer, one type of product or similar products from multiple manufacturers, or multiple different product types from multiple different manufacturers (e.g., materials issues). Information about emerging signals and safety communications is available on the Medical Device Safety[28] and CBER Safety & Availability (Biologics)[29] websites. FDA recommends reviewing any safety signals, emerging signals, or other safety information available prior to selecting a valid predicate device to support the 510(k) submission.

Once the submitter has identified a list of valid predicate devices, FDA recommends conducting a search of the Medical Device Safety and CBER Safety & Availability (Biologics) websites to assess whether any of the valid predicate devices have an associated use-related or design-related safety issue. For example, a signal was reported for duodenoscopes describing challenges in the adequacy of reprocessing instructions that resulted in a potential for disease transmission.[30] This signal resulted in an effort to replace traditionally reprocessed duodenoscopes with duodenoscopes which had innovative designs to enhance safety, including designs with disposable caps or distal ends. FDA considers it a best practice to select a valid predicate device that is not associated with emerging signals or safety communications that relate to unmitigated use-related or design-related safety issues whenever possible.

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[26] Available at https://www.fda.gov/medical-devices/medical-device-safety.
[27] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-notification-emerging-postmarket-medical-device-signals-emerging-signals.
[28] Available at https://www.fda.gov/medical-devices/medical-device-safety.
[29] Available at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics.
[30] Available at https://www.fda.gov/medical-devices/safety-communications/use-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication.

D. Predicate devices without an associated design-related recall

FDA recommends selecting a valid predicate device that has not been subject to a design-related recall.[31] Recalls are typically voluntary actions taken by a manufacturer or may be requested by FDA to correct or remove a violative product from the market.[32] A violative product is one in violation of the laws that FDA administers and against which FDA would initiate legal action. Recalls can occur due to design defects, manufacturing defects, or labeling defects.

Design-related recalls can indicate a fundamental flaw with the design of the device as cleared and commercially distributed. Design controls under 21 CFR 820.30 include a framework that requires manufacturers subject to these requirements to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.[33,34] When a design-related recall has been conducted for a device, adequate design control procedures, including but not limited to design input, output, verification, validation, and transfer may not have been adequately implemented through the design process. In some instances, the underlying root cause of the design related issues identified as part of a design-related recall may not be available or a correction of these design-related issues may not be possible. Further, although the methods and performance data provided in the 510(k) submission for the valid predicate device subject to a subsequent design-related recall were sufficient to support a substantial equivalence determination at that time of 510(k) clearance, utilization of such a valid predicate device may not be ideal to use for future 510(k) submissions.

Once the submitter has identified a list of valid predicate devices, FDA recommends conducting a search of the Medical Device Recalls Database to assess whether any of the valid predicate devices have an associated recall. For example, the recall of a coronary catheter tip for fracture could be associated with a change in the manufacturing process or with the materials used in the design of the catheter. If a recall is associated with the materials used in the catheter, this could be considered a design-related recall when it is due to an inadequacy of that material to meet user

[31] The Medical Device Recalls Database is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm, and includes recalls classified since November 2002.

[32] While FDA focuses on voluntary recalls conducted under 21 CFR Part 7, FDA may, after providing the appropriate person with an opportunity to consult with the Agency, also require that a manufacturer recall their device when the criteria are met under 21 CFR Part 810.

[33] For devices subject to 510(k) requirements, design controls apply to class II devices and those class I devices listed in 21 CFR 820.30(a)(2).

[34] On February 23, 2022, FDA proposed to amend the device Quality System Regulation, 21 CFR Part 820, to align more closely with international consensus standards for devices (87 FR 10119; available at https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments). Specifically, FDA proposed to withdraw the majority of the current requirements in Part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems for regulatory purposes, in Part 820. As stated in that proposed rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current Part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. FDA intends to finalize this proposed rule expeditiously. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR Part 820 in this guidance to be consistent with that rule.

needs and intended uses. The material used in the design of this catheter and the testing conducted on the predicate device did not adequately mitigate against the risk of tip fracture, resulting in a design-related recall. FDA considers it a best practice to select a valid predicate device that is not associated with a design-related recall whenever possible.

VI. Improving the Transparency of Predicate Devices

The 510(k) Summary is a document that provides an adequate summary of any information respecting safety and effectiveness and must include all the elements identified in 21 CFR 807.92.[35] A 510(k) Summary must be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence (21 CFR 807.92(a)). In Appendix B of the 510(k) Program Guidance, FDA describes the requirements of the content to be included in a 510(k) Summary, in accordance with 21 CFR 807.92, and provides recommendations on the information to be included in a 510(k) Summary to ensure compliance with 21 CFR 807.92 and consistency in the level of information conveyed and captured in the 510(k) Summaries that are available to the public on FDA's website.

In an effort to improve the transparency and predictability of the 510(k) program and to ensure that the 510(k) Summary reflects the information provided in a 510(k) submission to support a substantial equivalence determination, FDA stated in the 510(k) Program Guidance that the Agency intends to verify the accuracy and completeness of the information included in a 510(k) Summary.

Although the 510(k) Summary is a document drafted by the submitter and is included in the 510(k), revisions to the 510(k) Summary may be necessary to accurately reflect FDA's decision-making process. As stated in the 510(k) Program Guidance, and consistent with 21 CFR 807.92(b)(1), 510(k) Summaries shall include a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

FDA recommends that submitters include a narrative explaining their selection of the predicate device(s) used in support of the 510(k) submission in their draft 510(k) Summary submitted with their original 510(k).[36] FDA recommends this narrative include a discussion of how the best practices described in Section V of this guidance were used to select the predicate device(s) proposed for use in the 510(k) submission. This recommendation is intended to promote transparency to the public regarding the process of selecting a predicate device using these best practices.

When a submitter cannot identify a valid predicate device(s) that is consistent with any of the best practices discussed in Section V of this guidance, FDA recommends that the submitter

[35] As specified in 21 CFR 807.87(h), a 510(k) Statement as described in 21 CFR 807.93 may be provided in lieu of a 510(k) Summary. However, in order to facilitate transparency, FDA encourages all submitters to utilize the 510(k) Summary option.

[36] As described in Appendix C of the 510(k) Program Guidance, this information is provided in the Comparison of Technological Characteristics with the Predicate Device of the 510(k) Summary.

include a statement in their 510(k) Summary that a valid predicate that is consistent with the best practices was not available. FDA recommends that the submitter also use the Performance Data Section of the 510(k) Summary to describe the ways performance testing was conducted to address any known safety or effectiveness concerns with the predicate device used to support the 510(k) submission.[37]

VII. Examples

The following are illustrative examples that are intended to exemplify how the best practices identified in Section V of this guidance for selecting a valid predicate device can be used. These examples do not necessarily account for every possible detail, risk, or consideration that a submitter should consider when selecting the predicate device used in support of the 510(k) submission. These examples also include different formats that could be used depending on the number of valid predicate devices available for use to support the 510(k) submission.

Example 1

A submitter is preparing a 510(k) submission for a coronary guidewire, Guidewire X. The submitter identified four valid predicate devices, all of which have the same intended use as Guidewire X and any differences in technological characteristics do not raise different questions of safety and effectiveness. The submitter included the following table in their 510(k) submission, along with their rationale for selecting Predicate 4 as the predicate device used to support their 510(k) submission:

[37] Section 518A of the FD&C Act directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. Consistent with the 510(k) Program Guidance, FDA believes that providing greater transparency on recalled devices is one way to help achieve this directive.

Valid Predicate Device	A – Well-established methods	B – Meets or exceeds expected predicate performance	C – Unmitigated use-related or design-related safety issues	D – Associated design-related recall
1	Used internal methods that are not widely available and accepted	High frequency of fractures reported in MDRs/MedSun reports	Safety communication found on FDA's website	No design-related recall identified
2	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	Design-related recall identified in FDA's database
3	Used outdated methods in a subsequently superseded FDA guidance document	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified
4	Used updated methods from current FDA guidance document	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified

In their draft 510(k) Summary, the submitter includes a brief narrative describing the above selection process in the proposed 510(k) Summary. The submitter's draft 510(k) Summary also includes a discussion that the selected predicate used well-established methods from a current FDA guidance document, discusses the frequency of reported adverse events, and states that there are no known unmitigated use-related or design-related safety issues or design-related recalls.

Example 2

A submitter is preparing a 510(k) submission for a bone sonometer, Bone Sonometer X. The submitter identified only one valid predicate device, which has the same intended use as bone sonometer X and any differences in technological characteristics do not raise different questions of safety and effectiveness. The valid predicate device, Predicate 1, used the currently FDA-recognized versions of applicable consensus standards, has an expected frequency of reported events, had no known unmitigated use-related or design-related safety issues before submission of the device-related recall, but has been associated with a design-related recall.

The submitter referenced Predicate 1 as their predicate device in their 510(k) submission, along with a statement that Predicate 1 was the only valid predicate device that could be identified. The submitter also described the ways performance testing was conducted to address the safety

concerns relevant to the design-related recall associated with Predicate 1 and the measures taken to mitigate those safety concerns in the subject device.

In their draft 510(k) Summary, the submitter identified that the predicate device used to support the 510(k) submission has been the subject of a design-related recall, but also included a brief narrative describing the selection process in the proposed 510(k) Summary. The sponsor also included a summary of how their performance testing provided in the 510(k) addressed the safety concerns relevant to Predicate 1's design-related recall in the Performance Data section of the draft 510(k) Summary.

Example 3

A submitter is preparing a 510(k) submission for an intervertebral fusion device (IFD), IFD X. The submitter identified two valid predicate devices, both of which have the same intended use as IFD X and any differences in technological characteristics do not raise different questions of safety and effectiveness. Predicate 1 has been on the market for 15 years and Predicate 2 has been on the market for 3 years and both devices are still in clinical use. The submitter included the following table in their 510(k) submission, along with their rationale describing that while Predicate 2 also uses the best practices for selecting a predicate device, Predicate 1 was selected as the predicate device used to support the 510(k) submission because it has a well-established safety profile due to a longer duration of device use.

Valid Predicate Device	**A – Well-established methods**	**B – Meets or exceeds expected predicate performance**	**C – Unmitigated use-related or design-related safety issues**	**D – Associated design-related recall**
1	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events. History of safe use established due to duration of device on the market.	No known unmitigated use-related or design-related safety issues	No design-related recall identified
2	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified

In their draft 510(k) Summary, the submitter includes a brief narrative describing the above selection process in the proposed 510(k) Summary. The submitter's draft 510(k) Summary also includes a discussion that the predicate used to support the 510(k) submission used well-established methods for IFDs, discusses the frequency of reported adverse events, including that the device has a well-established safety profile through a history of safe use due to its longer duration on the market, and states that there are no known unmitigated use-related or design-related safety issues or associated design-related recalls.