Contains Nonbinding Recommendations

FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact the Office of Regulatory Programs/Division of Submission Support/510(k), De Novo, 513(g), Device Determinations and Custom Devices Lifecycle Team at (301) 796-5640, or by email to 510k_program@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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Preface

Public Comment

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Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1219 and complete title of the guidance in the request.

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FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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

The Medical Device User Fee Amendments of 2022[1] (MDUFA V) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2022, including premarket notification submissions (510(k)s). The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the device review process to meet certain performance goals and implement improvements for the medical device review process.

Performance goals were negotiated and agreed to under MDUFA V for 510(k)s received in FY 2023-2027. These performance goals and process improvements are outlined in the letter from the Secretary of Health and Human Services to Congress[2] (MDUFA V Commitment Letter) and are further described below.

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

[1] See Title II of the FDA User Fee Reauthorization Act of 2022 (Public Law 117-180).

[2] See 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization). The MDUFA V Commitment Letter is also available at https://www.fda.gov/media/158308/download.

use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

This guidance document describes:

- the different FDA actions that may be taken on premarket notifications (510(k)s);
- the effect each action has on goals under MDUFA IV for 510(k)s received in FY 2018-2022;
- the effect each action has on goals under MDUFA V for 510(k)s received in FY 2023-2027; and
- the different industry actions that may be taken on 510(k)s.

III. FDA Actions

FDA intends to begin substantive review of a 510(k) after the submission is accepted per the refuse to accept (RTA) criteria outlined in the guidance "Refuse to Accept Policy for 510(k)s,"[3] or passes the technical screening for an electronic submission (eSubmission) submitted using the electronic Submission Template and Resource (eSTAR).[4,5] After receipt, FDA may seek to verify that the submission type is correct during the RTA/technical screening period. If this initial verification reveals the submission is an incorrect type (e.g., a Special 510(k) should be converted to a Traditional 510(k)), FDA will place the submission on hold to allow the appropriate submission type to be submitted. The review clock will begin on the date the correct submission type is received for submissions that pass RTA or technical screening review. After FDA conducts a substantive review of the submission, FDA may take any of the following actions (21 CFR 807.100(a)):

- issue an order declaring a device substantially equivalent (SE) to a legally marketed predicate device (SE letter);
- issue an order declaring a device not substantially equivalent (NSE) to any legally marketed predicate device (NSE letter);

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks

[4] See FDA's guidance "Electronic Submission Template for Medical Device 510(k) Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions, and FDA's website regarding the eSTAR program, available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program. The website provides current information regarding the eSTAR program for CDRH and CBER.

[5] eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of 510(k) submissions as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

- issue a request for additional information (AI request); or
- advise the submitter that the 510(k) submission is not required (i.e., the product is not regulated as a device or the device is exempt from the premarket notification requirements of the FD&C Act).

Further, in accordance with 21 CFR 807.87(m), the Agency may consider a 510(k) to be withdrawn if additional information is not provided within 30 days following issuance of an AI request. In this instance, FDA may issue a notice of withdrawal. A notice of withdrawal is sometimes referred to as a "deletion letter." The term "deletion" is used to differentiate a withdrawal under 21 CFR 807.87(m) from a request to withdraw a pending 510(k) by the submitter. Please note that FDA's current policy is to allow a submitter 180 calendar days to respond to an AI request. See Section III.E Issue a Notice of Withdrawal for more details.

Of these FDA actions, issuing an SE letter and issuing an NSE letter are considered MDUFA decisions, as defined in the MDUFA IV[6] and MDUFA V[7] Commitment Letters.

The following sections describe the actions FDA may take on an accepted 510(k), explain when these actions may be appropriate, and discuss the effect that each action has on the review clock.

A. Issue an Order Declaring a Device SE

An order declaring a device to be SE (SE letter) is a letter issued to the 510(k) submitter stating that FDA has determined that the device described in the 510(k) submission is substantially equivalent to a legally marketed device.[8] An order declaring a device to be SE authorizes marketing of the device in the United States (U.S.), subject to specific statutory and regulatory requirements.

The criteria for determining a device to be SE are described in section 513(i) of the FD&C Act and in 21 CFR 807.100(b). Additional information relating to determinations of SE can be found in the guidance documents entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," [9] and "Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1)." [10]

An SE decision shuts off the review clock, marks the end of FDA review, and is considered a final action.

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[6] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization). The MDUFA IV Commitment Letter is also available at https://www.fda.gov/media/102699/download.

[7] https://www.fda.gov/media/158308/download

[8] See 21 CFR 807.92(a)(3) for the definition of "legally marketed device."

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

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/determination-intended-use-510k-devices-guidance-cdrh-staff-update-k98-1

B. Issue an Order Declaring a Device NSE

An order declaring a device to be NSE (NSE letter) is a letter issued to a 510(k) submitter stating that FDA has determined that the device described in the 510(k) submission is not substantially equivalent to any legally marketed device and may not be introduced into commercial distribution in the U.S.

In general, FDA issues an NSE letter in the following situations:

- no predicate device exists;
- the device has a new intended use compared to the identified predicate device;
- the device has different technological characteristics that raise different questions of safety and effectiveness than the identified predicate device; or
- the device has new indications for use or different technological characteristics than the identified predicate device, and required performance data was not provided to allow FDA to reach a substantial equivalence determination. This may include inadequate or inconclusive performance data (e.g., bench testing, clinical data, or animal data).

An NSE decision shuts off the review clock, marks the end of FDA review, and is considered a final action.

C. Request for Additional Information

FDA issues a request for additional information (AI request) when the 510(k) submission lacks the information necessary for the Agency to complete its review and to determine whether the device is SE or NSE (21 CFR 807.87). AI requests are issued by email with an attached document identifying deficiencies.[11] These requests inform the submitter that the 510(k) is being placed on hold pending receipt of a complete response to all of the identified deficiencies. The hold starts on the issue date of the AI request.

FDA generally issues an AI request when FDA believes the additional information needed from the submitter is not suitable for interactive review and/or cannot be provided within a reasonable timeframe (i.e., such that the review would be unduly delayed if the submission were not placed on hold).

An AI request is an interim action that stops the review clock and marks the end of an FDA review cycle. The review clock will resume upon the receipt of a complete response to the AI request.

[11] Please note that AI requests from CBER will be issued according to, "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.

D. Advise the Submitter that the 510(k) is Not Required

It is the manufacturer's responsibility to determine whether a 510(k) submission is required based on the FD&C Act, medical device regulations, and FDA-issued guidance documents. The Division of Industry and Consumer Education (DICE), the 510(k), De Novo, 513(g), Device Determinations and Custom Devices Lifecycle Team, the review division, and product classification resources on the CDRH Device Advice website, available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, can assist manufacturers in ascertaining whether a device is exempt by regulation.[12] Manufacturers may also obtain information regarding the regulatory status of a device or product by submitting a 513(g) request. For further information on 513(g) requests, please refer to the guidance document entitled "FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act."[13]

1. Not-a-Device Decision

A "not-a-device" letter informs the submitter that the product described in the 510(k) is not regulated as a device. FDA should issue a "not-a-device" letter when FDA has determined that the product described in the 510(k) submission does not meet the definition of "device" in section 201(h) of the FD&C Act.

The issuance of a "not-a-device" letter shuts off the review clock, marks the end of FDA review, and is considered a final action.

2. Exempt from 510(k) Decision

An "exempt" letter informs the 510(k) submitter that the device described in the 510(k) submission is classified as exempt from the premarket notification requirements of section 510(k) of the FD&C Act. FDA will issue an "exempt" letter, or otherwise advise the submitter, when FDA determines that the device described in the 510(k) submission is exempt by regulation from the premarket notification requirements of section 510(k) of the FD&C Act. Exemptions are found in 21 CFR 807.20(c), 807.65, and 807.85, as well as individual classification regulations (21 CFR Parts 862-892).

The issuance of an "exempt" letter shuts off the review clock, marks the end of FDA review, and is considered a final action.

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[12] For CBER submissions, please contact the Office of Communication, Outreach, and Development, the review division, and the product classification resources on the CDRH Device Advice website, available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

E. Issue a Notice of Withdrawal

A notice of withdrawal informs the 510(k) submitter that FDA considers the 510(k) submission to be withdrawn (21 CFR 807.87(m)). The notice of withdrawal represents an FDA decision to discontinue its review of the 510(k) submission because the submitter failed to submit a timely and complete response to an AI request that placed the submission on hold.

In accordance with 21 CFR 807.87(m), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide a complete response to an AI request within 30 days of that request. In the past, FDA has not strictly enforced this time frame and has allowed submitters additional time to respond to AI requests.

FDA intends to continue this practice of allowing additional time, not to exceed 180 calendar days from the date FDA issues the AI request, to submit a complete response. FDA considers a 510(k) submission to be withdrawn if FDA does not receive a complete response in a submission to all of the deficiencies in the AI request within 180 calendar days of the date of that AI request. Therefore, submitters are not required to submit written requests for extension from 30 calendar days to 180 calendar days.

If a 510(k) submission is withdrawn while the submission is on hold, an FDA notice of withdrawal does not affect the review clock. Issuance of a notice of withdrawal stops the review clock, marks the end of FDA review, and is considered a final action.

IV. 510(k) Performance Goals for MDUFA IV

The performance goals for 510(k) submissions received from FY 2018 through FY 2022 (the time frame defined for MDUFA IV) were defined in the MDUFA IV Commitment Letter.[14] Table 1 below summarizes the performance goals for 510(k) submissions, where 510(k) decisions include SE and NSE, and all review times are in FDA calendar days. Performance goals are applied to the MDUFA IV cohort of 510(k) submissions and include goals for Substantive Interaction, MDUFA decision, and Total Time to Decision.

The goals for Substantive Interaction and MDUFA decisions are in terms of FDA Days, which are defined in the MDUFA IV Commitment Letter as those calendar days when a submission is considered to be under review at the Agency for submissions that have been accepted. FDA Days begin on the date of receipt of the submission or the amendment to the submission that enables the submission to be accepted.

Total Time to Decision was a shared outcome goal for which FDA and industry performance were reported during MDUFA IV. FDA and submitters shared responsibility for this goal, which was intended to achieve an objective of a reduced average total time to a MDUFA decision (SE or NSE). This goal measures the total time to decision which includes the time

[14] https://www.fda.gov/media/102699/download

spent by FDA reviewing the application as well as the time spent by the applicant responding to questions from FDA.

The Total Time to Decision is the number of calendar days from the date of receipt of an accepted submission to a MDUFA decision. As defined in the MDUFA IV Commitment Letter, the average Total Time to Decision for 510(k) submissions was calculated as the trimmed mean of Total Times to Decision for 510(k) submissions within a closed cohort, excluding the highest 2% and the lowest 2% of values. A cohort is considered to be closed when 99% of the accepted submissions have reached a MDUFA decision.

Table 1. 510(k) Performance Goals Under MDUFA IV

Action	Review Time (FDA days)	Performance Level (by FY)				
		FY2018	FY2019	FY2020	FY2021	FY2022
Substantive Interaction	60	95%	95%	95%	95%	95%
MDUFA Decision (SE/NSE)	90	95%	95%	95%	95%	95%
		Total Time in Calendar Days				
Average Total Time to Decision		124	120	116	112	108

V. 510(k) Performance Goals for MDUFA V

The performance goals for 510(k) submissions received from FY 2023 through FY 2027 (MDUFA V) are defined in the MDUFA V Commitment Letter.[15] Performance goals and associated changes introduced under MDUFA III, MDUFA IV, and retained in MDUFA V include:

- most 510(k) submissions are subject to a user fee, and all 510(k) submissions need a valid eCopy[16] or electronic submission[17] in order to initiate a review;
- 510(k) submissions are subject to an Acceptance Review prior to being considered for substantive review;[18]

[15] https://www.fda.gov/media/158308/download

[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab

[18] Given that an electronic submission properly prepared with an electronic submission template should represent a complete submission, eSTAR submissions are not anticipated to undergo an RTA process. See Section V.B. for additional details.

- 510(k) submissions are subject to a Substantive Interaction (SI) Goal;
- 510(k) submissions are subject to a one-tier MDUFA decision goal (for FDA Days and Total Time to Decision); and
- for 510(k)s for which the MDUFA decision is exceeded by 10 calendar days, FDA will send a Missed MDUFA Decision (MMD) communication to the submitter.

Performance goals and associated changes introduced under MDUFA V include:

- revised goals for Substantive Interaction, MDUFA decision, and Total Time to Decision (see Table 2 below).

A. Submission

Most 510(k) submissions will be subject to a user fee as described in the guidance "User Fees and Refunds for Premarket Notification Submissions (510(k)s)"[19] and all 510(k)s will be subject to the requirement for an eCopy or an electronic submission using eSTAR. Please see the guidance entitled "eCopy Program for Medical Device Submissions,"[20] for more information about eCopy requirements and the guidance entitled "Electronic Submission Template for Medical Device 510(k) Submissions"[21] for more information about eSTAR requirements for 510(k) submissions. 510(k) submissions will not be processed and distributed to the appropriate Division for review without confirmation of user fee payment (or applicability of a user fee exception), and a valid eCopy or eSTAR.

B. Acceptance Review

Within 15 calendar days of receipt, FDA will conduct an Acceptance Review to determine whether the submission is complete and can be accepted for substantive review.[22] If FDA refuses to accept a 510(k), FDA will notify the submitter within 15 calendar days that the submission has not been accepted. The notification will identify those items that are the basis for the refuse to accept (RTA) decision and are therefore necessary for the submission to be considered accepted. The submission will be placed on hold and the review clock will not start until the missing elements are provided. For additional information, please refer to the guidance, "Refuse to Accept Policy for 510(k)s."[23]

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[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-notification-submissions-510ks

[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions

[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions

[22] In the case of a government closure during the 15-day review period, the review period may be extended by a comparable number of business days that the FDA buildings are closed. If the submitter receives an automated notice that the acceptance review was not completed because the screening period has exceeded 15 calendar days, FDA may send a correction notice to the submitter.

[23] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks

This communication represents a preliminary review of the submission and is not indicative of deficiencies that may be identified later in the review cycle.

Given that an electronic submission properly prepared with an electronic submission template should represent a complete submission,[24] eSTAR submissions are not anticipated to undergo an RTA process.[25] However, FDA intends to employ a virus scanning and technical screening process for an eSTAR. The technical screening process is anticipated to occur within 15 calendar days of FDA receiving the 510(k) eSTAR. FDA intends to only begin the technical screening for 510(k) electronic submissions where the appropriate user fee has been paid. If the eSTAR is not complete when submitted, FDA will notify the submitter via email[26] and identify the incomplete information, and the 510(k) will be placed and remain on hold until a complete replacement eSTAR is submitted to FDA. The technical screening review time does not impact the review clock for submissions that pass the technical screening. For a submission that passes technical screening, the review clock starts on the day the submission was received by FDA.

C. Substantive Review

Once the submission has been accepted for review (i.e., after the RTA or technical screening phase of review), FDA will conduct the substantive review. During the substantive review, FDA will generally communicate with the submitter through a Substantive Interaction within 60 calendar days of receipt of the accepted 510(k) submission. The Substantive Interaction communication can be an AI request or an email stating that FDA will continue to resolve any outstanding deficiencies via Interactive Review. An SE letter issued prior to the Substantive Interaction goal date will also qualify as a Substantive Interaction for purposes of meeting the MDUFA V goal.

Following a Substantive Interaction, FDA intends to work with the submitter via Interactive Review to reach a MDUFA decision.

D. MDUFA V Goals

MDUFA V includes goals for Substantive Interaction, MDUFA decision, and Total Time to Decision (see Table 2 below).

[24] After a submitter completes all necessary sections in their eSTAR file correctly, the status message at the top of the PDF will indicate "eSTAR Complete" to represent a complete submission.
[25] For more information on the RTA process, please see "Refuse to Accept Policy for 510(k)s" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[26] For additional information about email communications with CBER, please see the "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.

Table 2. 510(k) Performance Goals Under MDUFA V

Action	Review Time (FDA days)	Performance Level (by FY)				
		FY2023	FY2024	FY2025	FY2026	FY2027
Substantive Interaction	60	95%	95%	95%	95%	95%
MDUFA Decision (SE/NSE)	90	95%	95%	95%	95%	95%
		Total Time in Calendar Days				
Average Total Time to Decision		128	124	112	112 (108)[27]	112 (108)[28]

Note that the methods by which goals for Substantive Interaction and MDUFA decision are assessed have not changed from MDUFA IV.

E. Missed MDUFA Decision Communication

For all 510(k)s that do not reach a MDUFA decision within 100 FDA days (i.e., 10 calendar days after the MDUFA goal), FDA will provide a missed MDUFA decision communication, which is written feedback to the submitter to be discussed in a meeting or teleconference, including the major outstanding review topic areas or other reasons that are preventing FDA from reaching a final decision as well as an estimated date of completion.

VI. Submitter Actions

Actions taken by the submitter of a pending 510(k) may include submission of a response to FDA's AI request (i.e., not a request made via Interactive Review) or withdrawal of the entire 510(k) submission (either by request or by not responding to an FDA AI request within 180 calendar days). The information below describes the actions a submitter may take and the effect each action has on the review clock.

As with the original 510(k) submission, any submission of additional information to a 510(k) will need to include an eCopy or eSTAR as part of the submission for the submission to be

[27] The goal will be adjusted if the conditions of Section III.A of the MDUFA V Commitment Letter are met. For additional information, see Section III.A of the MDUFA V Commitment Letter, available at https://www.fda.gov/media/158308/download.

[28] The goal will be adjusted if the conditions of Section III.A of the MDUFA V Commitment Letter are met. For additional information, see Section III.A of the MDUFA V Commitment Letter, available at https://www.fda.gov/media/158308/download.

processed.[29]

A. Response to an AI Request

A response to an FDA AI request is the submission of additional information, addressing all of the deficiencies identified in that AI request, that allows FDA to continue or complete the substantive review and reach a decision on the 510(k) submission.

The submitter should provide a complete response to an AI request from FDA. The response should address all of the deficiencies identified by FDA in its AI request to be considered a complete response.

The submitter's submission of a response to an AI request is an action that, upon receipt by FDA, resumes the review clock (i.e., the 90-day review clock resumes upon receipt of the additional information).

If FDA determines that the submitter has not addressed one or more of the deficiencies identified in the AI request, the review cycle will be terminated until FDA receives a response addressing the remaining deficiencies. In such a case, FDA informs the submitter by email that the response is incomplete and the 510(k) will be placed back on hold as of the date of the original AI request; therefore, the review clock has not resumed. The submitter will have 180 calendar days from the date of the original AI request in which to submit a complete response, or the entire 510(k) will be considered to be withdrawn (21 CFR 807.87(m)).

If the submitter submits unsolicited additional information (i.e., not prompted by the FDA) that constitutes a new indication for use or a new or different technology, the submitter will be required to submit a new 510(k) and the associated fee. This is because the unsolicited information would essentially require FDA to restart the substantive review.

B. Request for Withdrawal of the 510(k) Submission

A request to withdraw an entire 510(k) informs FDA of the submitter's intent to discontinue its pursuit of FDA review of the 510(k) submission.

The 510(k) submitter may request withdrawal of the entire pending 510(k) submission at any time, and for any reason, after it is submitted for review, but before FDA renders its final decision. FDA does not consider requests for withdrawal after a final decision has been rendered.

The request to withdraw an entire pending 510(k) submission shuts off the review clock, marks the end of FDA review, and is considered a final action. If the 510(k) is under review

[29] https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper-format-cber-regulated-products

at the time FDA receives the withdrawal request, the review clock will stop on that date. If the 510(k) is on hold at the time FDA receives the withdrawal request, the review clock will remain stopped as of the date the 510(k) was last placed on hold.

C. Extensions of Time to Respond to an AI Request

In accordance with 21 CFR 807.87(m), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of a request. As explained above in Section III.E, FDA generally permits submitters additional time to respond to such requests.

FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension.

However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(m) if FDA does not receive a complete response in a submission to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request.