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User Fees and Refunds for Premarket Notification Submissions (510(k)s)

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes "User Fees and Refunds for Premarket Notification Submissions (510(k)s)" issued on October 2, 2017.

For questions regarding submissions to the Center for Devices and Radiological Health (CDRH), 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 at OPEQSubmissionSupport@fda.hhs.gov.

For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), 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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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852-1740. Identify all comments with the docket number FDA-2003-D-0198. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1511 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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User Fees and Refunds for Premarket Notification Submissions (510(k)s)

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 (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).[2] The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process as outlined in the letter from the Secretary of Health and Human Services to Congress.[3]

The purpose of this guidance document is to identify: (1) the types of 510(k)s subject to user fees, (2) exceptions to user fees, and (3) the actions that may result in refunds of user fees that have been paid. This document incorporates the impact of process improvements from MDUFA V.

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] For additional information on medical device user fees, please see https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.
[3] 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. Frequently Asked Questions (FAQ)

1. Are all 510(k)s subject to user fees?

Most 510(k) submissions are subject to user fees. Section 738(a)(2)(A)(viii) of the FD&C Act, requires the submitter to pay a user fee for any 510(k) (Traditional, Abbreviated, or Special[4]) that you submit to FDA, unless you qualify for one of the exceptions listed below. You will not have to pay a user fee for your 510(k) if:

- your submission is reviewed by an FDA-accredited third party[5] who submits it to FDA with the third party's recommendation concerning whether your device is substantially equivalent to a legally-marketed predicate; see section 738(a)(2)(B)(iv) of the FD&C Act; or
- your submission is for a device intended solely for a pediatric population; see section 738(a)(2)(B)(v)(I) of the FD&C Act;[6] or
- you are a state or federal government entity and your device will not be distributed commercially; see section 738(a)(2)(B)(iii) of the FD&C Act.

Refer to the Appendix for a summary of when a 510(k) is subject to user fees (Table 1).

2. What are the 510(k) user fees?

User fees for the current fiscal year are established under section 738 of the FD&C Act and shown on the FDA MDUFA User Fees website at https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

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[4] These terms are explained in "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k, "The Abbreviated 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program, or "The Special 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program, respectively.

[5] See section 523 of the FD&C Act. For general information concerning third-party review of 510(k)s, see "510(k) Third Party Review Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program .

[6] For guidance on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect pediatric subjects during the course of clinical trials involving such devices, see "Premarket Assessment of Pediatric Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices.

3. How do I pay my user fee(s)?

As outlined below, there are three ways you may submit your user fee.[7] Be sure to include the Payment Identification Number (PIN, beginning with MD)[8] and the FDA P.O. Box on your check, bank draft, or U.S. Postal Money Order. Also, you should include a printed copy of your User Fee Cover Sheet (Form FDA 3601, accessible through FDA's User Fee System at https://userfees.fda.gov/OA_HTML/fdaCAcdLogin.jsp) with your payment.

1) Preferred method – Credit Card or Electronic Check (ACH): FDA has partnered with the U.S. Department of the Treasury to utilize https://www.pay.gov/, a Web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. To pay online, select the "Pay Now" button. Credit card transactions for cover sheets are limited to $24,999.99.

2) Check: All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Please write your unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, on the check and mail the check to the appropriate address listed below. FDA will not be able to process your payment correctly without your cover sheet PIN.

   Check payments by mail:
   Food and Drug Administration
   P.O. Box 979033
   St. Louis, MO 63197-9000
   Note: In no case should payment be submitted with the 510(k).

   Check payments delivered by a courier service:
   U.S. Bank
   ATTN: Government Lockbox 979033
   1005 Convention Plaza
   St. Louis, MO 63101
   Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact US Bank at (314) 418-4013.

3) Wire Transfer: Please include your submission's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, in your wire transfer. Without the PIN your payment may not be applied to your cover sheet and review of your submission will be delayed.

   The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your cover sheet is fully paid.

[7] Additional information regarding payment of user fees is available at https://userfees.fda.gov/OA_HTML/mdufmaFAQ.html.
[8] A PIN is obtained after creating a User Fee Cover Sheet and selecting "Submit Cover Sheet to FDA."

Wire transfer information:
US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045

FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33

4. If FDA has indicated that my device is eligible for third-party review, and my 510(k) was reviewed by a third party, but FDA later determines that my device is not eligible for review by the third party, will I have to pay a user fee?

No. You do not have to pay a user fee if FDA had indicated your device is eligible for third-party review but determines during the course of review of the third-party submission that your device is not appropriate for third-party review. Among the reasons FDA may later determine that a particular device is not appropriate for third-party review are:[9]

- The device requires clinical data to demonstrate substantial equivalence; see section 523(a)(3)(A)(iii) of the Act.
- The device or combination product requires multi-Center review or consultation (e.g., 510(k)s for drug/device combination products).

5. If my 510(k) was reviewed by a third party, will I have to pay a user fee if my device was not eligible for review by the third party?

Yes. If you employ a third-party reviewer to review a device that is not eligible for third-party review, the exception is not applicable and you will have to pay the appropriate 510(k) user fee in effect for your submission.

Please refer to FDA's guidance 510(k) Third Party Review Program[10] for a list of factors used in determining device type eligibility for the third-party review program.

[9] Each third-party review of a 510(k) must meet the statutory eligibility requirements set out in section 523 of the Act. The two criteria identified here are the two most likely to be subject to errors of interpretation.
[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program

6. What are the circumstances when FDA will refund my user fee payment?

Statutory exception: If we determine that you have mistakenly paid a fee for a type of 510(k) that does not require a fee because of a statutory exception (see FAQ 1 and Appendix 1 (Table 1)), FDA will refund your payment for that submission upon request.

Failure to supply a valid electronic copy (eCopy) or an electronic submission template: See FAQ 9 and Appendix 1 (Table 2).

Withdrawal of submission if acceptance criteria are not met: See FAQ 10 and Appendix 1 (Table 2).

Withdrawal of an electronic submission template which did not pass technical screening and is placed on hold: See FAQ 11 and Appendix 1 (Table 2).

7. What are the circumstances when FDA will not refund my user fee payment?

4) *Your 510(k) submission is accepted for review*: After the user fee is paid and a valid eCopy is provided to FDA, FDA intends to conduct an acceptance review of your submission within 15 calendar days, as detailed in the FDA guidance, "Refuse to Accept Policy for 510(k)s."[11] If the 510(k) submission is accepted for review, we will not refund your user fee payment.

5) *Your 510(k) submitted via eSTAR has passed technical screening:* After the user fee is paid for a 510(k) submitted via the electronic Submission Template And Resource (eSTAR),[12,13] FDA intends to conduct a virus screening and technical screening of your submission within 15 calendar days, as detailed in the FDA guidance "Electronic Submission Template for Medical Device 510(k) Submissions."[14] If the 510(k) submission passes the technical screening process, we will not refund your user fee payment.

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

[12] For more information see FDA 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 (https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program). This website provides current information regarding the eSTAR program for CDRH and CBER.

[13] 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."

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

6) *Device is exempt from 510(k) requirements of the Act:* If you submit a 510(k) for a device that is exempt from the requirements of section 510(k) of the FD&C Act, we will not refund your fee payment. It is your responsibility to review the classification regulations[15] that pertain to your device and to determine whether a regulation exempts your device from the 510(k) requirements. Consultation with FDA personnel before submitting 510(k)s for products that may not require review will serve to conserve both FDA and industry resources.[16]

7) *Not a device:* If you submit a 510(k) for a product that FDA determines does not meet the definition of a device under section 201(h) of the FD&C Act, or is not a combination product with a device constituent part, we will not refund your fee payment.

8) *Change or modification to a device:* FDA reviews all 510(k) submissions, including those for a change to a legally marketed device, for determination of substantial equivalence. [17] Therefore, FDA does not intend to refund user fees if, for example, a manufacturer later decides that the change may not have been of a type that required a new 510(k) and wishes to withdraw the submission. FDA encourages manufacturers who intend to modify a legally marketed device to consult the FDA guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[18] Also, note that a guidance document applicable to a specific type of device would supersede the above referenced general guidance document.

In addition, in order to obtain information regarding the class in which a device has been classified or the requirements applicable to a device, a manufacturer may submit a request under section 513(g) of the FD&C Act. For more information on submitting a 513(g) Request for Information, please see the FDA guidance "User Fees for 513(g) Requests for Information."[19]

8. Do I have to pay for a new submission if I previously received a Not Substantially Equivalent (NSE) determination for my device?

Yes, unless a statutory exception applies. Any new submission for a device found NSE is

[15] See 21 CFR parts 862-892.

[16] Among the resources to help you ascertain whether your device is exempt by regulation are the Division of Industry and Consumer Education (DICE) for CDRH and the Manufacturers Assistance and Technical Training Branch (MATTB) for CBER, the CDRH or CBER review staff; and product classification resources on the CDRH website, available at https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device. DICE can be reached by phone at (800) 638-2041 or (301) 796-7100, or by email at DICE@fda.hhs.gov. MATTB can be reached at (800) 835-4709 or (240) 402 8020, or by email at Industry.Biologics@fda.hhs.gov.

[17] See 21 CFR 807.81.

[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information

subject to the fee associated with the submission type, if the type is subject to fees.[20]

As described in the FDA guidance, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals,"[21] if we determine your device is NSE for one of the following three reasons:

- no predicate device, as defined in 21 CFR 807.92(a)(3), exists,
- your device has a new intended use compared to the predicate, or
- your device has different technological characteristics that raise different questions of safety and effectiveness;[22]

You have three options: (1) You may petition for Evaluation of Automatic Class III Designation (De Novo classification request under section 513(f)(2)(A) of the FD&C Act, (2) submit a humanitarian device exemption (HDE) application, or (3) submit a premarket approval application (PMA), HDEs are not subject to user fees.[23] However, if you submit a PMA or De Novo request, FDA will assess the PMA or De Novo user fee at the time of the submission (https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa).

We may determine that your device is NSE based on the fact that the performance data provided in your submission did not demonstrate your device to be at least as safe and effective as a legally marketed device of that type. You may submit a new 510(k) if you believe you have additional data showing that your device is substantially equivalent to a legally marketed predicate device. Because FDA considers this submission a new 510(k), we will assess the fee in effect for a 510(k) at the time of the new 510(k) submission. This information is summarized in the Appendix (Table 3).

9. If FDA considers my 510(k) withdrawn because I failed to supply a valid electronic copy (eCopy) or an eSTAR, will FDA refund my fee payment?

Yes. Section 745A(b) of the FD&C Act provides statutory authority to require eCopies or submission solely in electronic format (e.g., eSTAR) after issuance of final guidance.[24] As

[20] Section 738(a)(2)(A) of the FD&C Act.
[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals
[22] See section 513(i) of the FD&C Act
[23] Section 738(a)(2)(B)(i) of the FD&C Act.
[24] See Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals

outlined in FDA's guidance "eCopy Program for Medical Device Submissions,"[25] if FDA receives an eCopy that cannot be accepted because it does not meet our technical standards, the omission or reasons for that failure will be communicated to you in writing to aid in your creation of a valid replacement eCopy. If a valid eCopy of an original submission is not received within 180 calendar days of this notification, the submission will be deleted from our system and FDA will refund the fee paid upon request. If you decide not to submit a valid replacement eCopy of your original submission in response to the eCopy hold notification, you may send a written request to withdraw your submission before receiving a deletion letter and request a refund of the fee paid. FDA intends to follow a similar process should an eSTAR be submitted that does not pass an automatic verification process.[26]

Note that your fee will not be refunded if you fail to provide a valid eCopy or an eSTAR for a response to an additional information request after the 510(k) has been accepted for review (see FAQ 16 and Appendix 1 (Table 2)).

10. If acceptance criteria are not met for my 510(k) submission, will FDA refund my user fee payment?

Yes. FDA intends to conduct an acceptance review of your submission as detailed in the FDA guidance, "Refuse to Accept Policy for 510(k)s."[27] If FDA refuses to accept your submission, you will be notified within 15 calendar days of receipt that your submission has not been accepted. You may submit additional information to the 510(k) submission to address the reasons for the refusal without submitting a new user fee. Alternatively, you may request to withdraw the submission and request a refund of the fee paid if you decide not to provide additional information. See FAQ 17 below for more information on how to request a refund.

11. Will FDA refund the user fee if I submit a 510(k) using eSTAR, the eSTAR does not pass technical screening and is placed on hold, and I withdraw the 510(k) submission?

Yes. You will be notified within 15 calendar days of receipt if your eSTAR does not pass technical screening and is placed on hold. You may submit additional information to the 510(k) submission to address the reasons for the technical screening hold without submitting a new user fee. Alternatively, you may request to withdraw the submission and request a refund of the fee paid if you decide not to provide additional information.

[25] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions
[26] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[27] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks

12. Will FDA refund the user fee if I submit an eSTAR and the eSTAR passes technical screening?

No. Given that an electronic submission properly prepared with an electronic submission template (e.g., eSTAR)) should represent a complete submission,[28] eSTARs are not anticipated to undergo a refuse to accept (RTA) process.[29] 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 begin the technical screening for 510(k) electronic submissions after confirmation of user fee payment. If the eSTAR is not complete when submitted, FDA will notify the submitter via email[30] 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. FDA will not refund user fees paid for eSTARs that have passed technical screening.

13. Do I have to pay an additional fee if I submit additional information to a pending 510(k)?

No. There are no fees when you submit additional information to a 510(k) for which FDA has not yet rendered a final decision. However, if you submit unsolicited additional information that constitutes a *new indication for use* or *new or different technology*, (i.e., changes that would typically require submission of a new 510(k)),[31] you will be required to submit a new 510(k) and pay the associated fee.

14. Will FDA refund the user fee if I withdraw my 510(k) after it has been accepted for review?

No. The FD&C Act does not identify withdrawal of a 510(k) submission under substantive review as a basis for a refund; see section 738(a)(2)(D) of the FD&C Act. Although the FD&C Act provides FDA limited authority to provide a partial refund when a *premarket application, premarket report, or supplement* [32] is withdrawn after filing,[33] that authority does not extend to 510(k) submissions.

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[28] 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.
[29] 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.
[30] 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.
[31] See FDA's guidance 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

[32] These terms are defined by sections 737(1), 737(2), and 737(4)(A), respectively, of the FD&C Act.
[33] See section 738(a)(2)(D)(iii) of the FD&C Act.

15. Must I pay a new user fee if I withdraw and resubmit my 510(k) after it has been accepted for review (or my eSTAR passes technical screening)?

Yes. If you withdraw your 510(k) submission after it has been accepted for review (or, for an eSTAR, after it passes technical screening), and resubmit at a later time, you must pay the fee in effect at the time of the new submission.

16. If FDA considers my 510(k) withdrawn after it has been accepted because I failed to supply requested information, will FDA require a new user fee if I resubmit my 510(k)?

Yes. If you fail to respond to an FDA request for additional information within the specified timeframe, FDA will issue a notice of withdrawal stating that it considers your 510(k) to be withdrawn.[34] You must pay the 510(k) fee in effect at the time of the new 510(k) submission.

17. If eligible, how do I request a refund?

To facilitate the Agency's orderly issuance of refunds, you should submit a written request[35] for a refund to the appropriate Center in FDA within 180 calendar days after the fee was due.

For devices regulated by CDRH, requests for refunds should be submitted to the current mailing address displayed on the website https://www.fda.gov/cdrhsubmissionaddress.

For devices regulated by CBER, requests for refunds should be submitted to the current mailing address displayed on the website https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper.

[34] See 21 CFR 807.87(m) and FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals

[35] The user fee payment refund request form is available at https://www.fda.gov/media/96650/download.

Appendix: Information Summary Tables

Table 1. When is a 510(k) Subject to a User Fee?

510(k) Submission Type	510(k) Fee Required?
Original 510(k) submission	Yes
Additional information provided for existing 510(k) in response to Refuse to Accept notification	No
Additional information for a pending 510(k)	No
510(k) submitted by a state or federal government sponsor *and* the device will not be commercially distributed	No
510(k) eligible for review *and* reviewed by an FDA-accredited third-party reviewer	No
510(k) intended solely for a pediatric population	No
510(k) submission for a device previously found NSE	Yes
510(k) resubmitted after it has been withdrawn	Yes

Table 2. When Will FDA Refund a 510(k) User Fee?

FDA Determination or Submitter Action	Will FDA Refund My Fee Payment?
FDA determines my 510(k) is not required. Basis for FDA's decision:	
• I qualify for one of the fee exceptions provided by section 738(a)(1)(B) of the Act	Yes
• My product is not a device	No
• My device is exempt from premarket notification requirements	No
FDA determines my device is "NSE."	No
I withdraw my 510(k) after acceptance for review.	No
FDA considers my 510(k) to be withdrawn after acceptance for review. See 21 CFR 807.87(m).	No
I fail to submit a valid eCopy or eSTAR before my original 510(k) is accepted for review.	Yes
I fail to submit a valid eCopy or eSTAR for a 510(k) response to an additional information request and FDA considers the 510(k) withdrawn.	No
FDA determines my submission does not meet the acceptance criteria during acceptance review.	Yes

FDA Determination or Submitter Action	Will FDA Refund My Fee Payment?
FDA determines my eSTAR does not pass technical screening and places the submission on hold.	Yes
I withdraw my eSTAR after it passes technical screening.	No

Table 3. What Fee Must I Pay for a New Device Submission Following a 510(k) "NSE" Determination?

Submission Type	Must I Pay a Fee?
New 510(k)	Yes. You must pay the applicable fee for a 510(k).
De Novo Request (see section 513(f)(2) of the Act)	Yes. You must pay the applicable fee for a De Novo.
Reclassification Petition	No.
PMA	Yes. You must pay the applicable fee for a PMA.
HDE	No.