Evolving 510(k) Program and De Novo Process

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U.S. FOOD & DRUG ADMINISTRATION

FDLI 2019
Evolving 510(k) Program and De Novo Process

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Outline

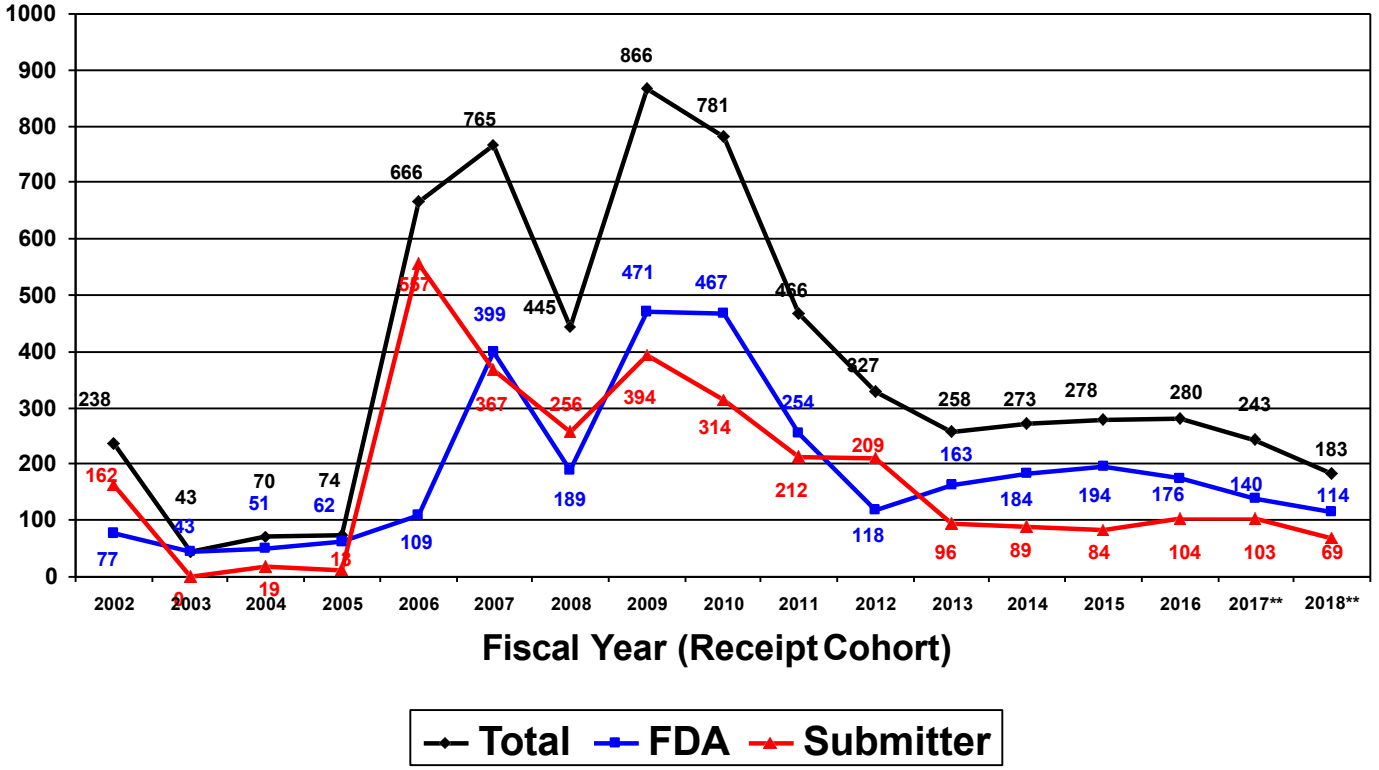
- History and Trends
- De Novo Proposed Rule
- De Novo Refuse to Accept (RTA) Guidance
- De Novo Discussion Points

De Novo History and Evolution

- FDAMA (1997) — *Created De Novo pathway*
  - FDASIA (2012) — *Added Direct De Novo option*
    - 21st Century Cures (2016) — *Added combination products*
      - FDARA (2017) — *Added user fees; created new guidances*
        - De Novo RTA — *Final guidance expected 2019*
        - De Novo Final Rule — *???*

Average Time to MDUFA Decision: De Novos*

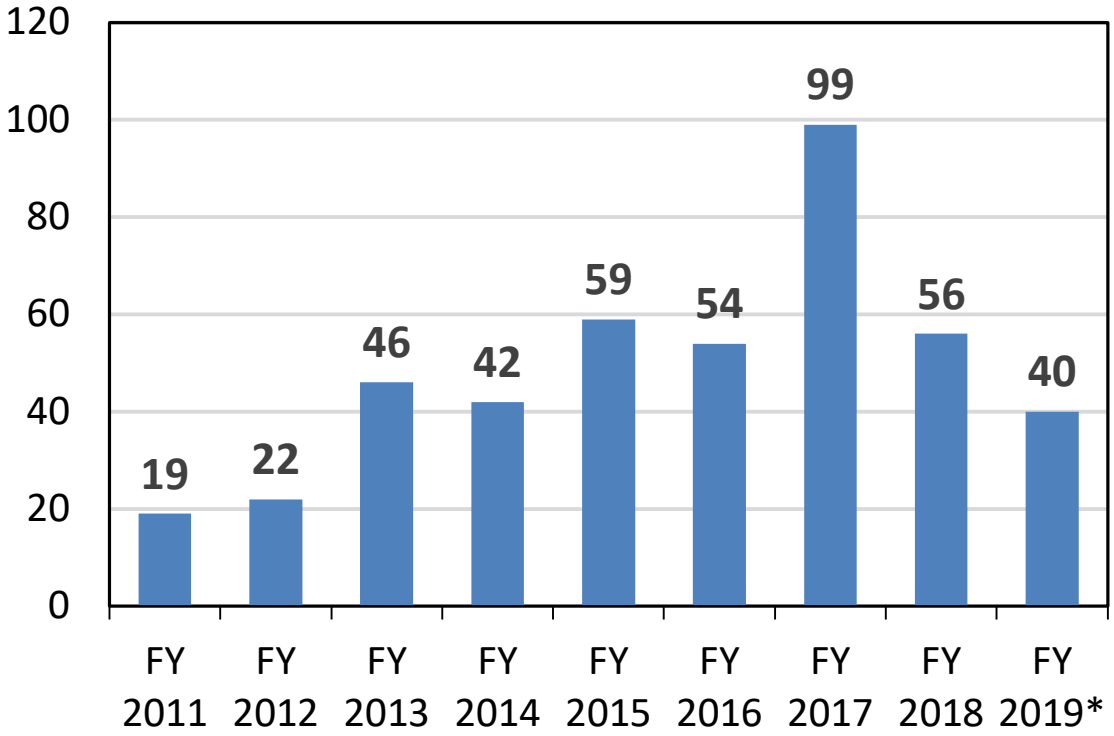
(Receipt Cohorts as of 12/31/2018)



* MDUFA (Grant/Decline/Withdrawal/Deletion) decisions only; times may not add to total due to rounding

** Cohort still open; percentage of cohort closed: FY2017: 95%; FY2018: 50%

De Novos Received In CDRH



* Open cohort (as of 4/23/2019)

Major Provisions in Proposed Rule

- **Purpose and Applicability:** Includes criteria for determining whether a device is eligible for De Novo classification.
- **Format and Content:** Identifies the basic structure and information/data required for inclusion in a De Novo request.
- **Acceptance:** Identifies the criteria for accepting a De Novo request for substantive review, including required content.
- **Procedures for Review:** Outlines the general procedures for review of a De Novo request and other actions that may take place during the review and prior to a final decision.
- **Actions on a De Novo Request:** Outlines criteria for granting/declining and the circumstances under which a De Novo may be withdrawn from FDA review.
- **Confidentiality:** Describes our practices for the conditions under which the confidentiality of a De Novo request is maintained.

De Novo Proposed Rule

- Clarify statutory authorities
- Codify procedures for De Novo classification
- Provide greater transparency and predictability
- Comment period closed March 7, 2019
  - Agency currently addressing submitted comments

Draft De Novo RTA Guidance

- **Purpose: Ensure De Novo request is acceptable for substantive review**
- Facilitates efficient and timely review
- Similar to RTA policies for 510(k) and PMA
  - Intend to complete RTA review within 15 calendar days of receiving De Novo
  - De Novo is considered accepted if RTA review is not completed within 15 calendar days
- Final RTA guidance anticipated to be in effect late 2019 with a 60-day implementation period
- Fulfills MDUFA IV commitment (“submission checklist”)

Draft De Novo RTA Guidance

Appendix A	Appendix B
Acceptance Checklist	**Recommended Content Checklist**
Required	Not Required
Examples: Intended use Device description Proposed special controls (if recommending class II)	*Examples:* Prior submissions Classification summary (eligibility) Device labeling

De Novo Discussion Points

- De Novo devices are at the center of current issues for novel and innovative medical device technologies
- Classification requires determination of reasonable assurance of safety and effectiveness, but granting a De Novo request is not a “clearance” or an “approval”
- Regulations created through De Novo classification set the stage for continuing innovation in 510(k) for devices with comparable intended uses, technologies, and risks
- Submit pre-submissions to discuss the regulatory landscape of devices with FDA and understand the risks to health associated with your intended use or technology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Pre-Market Notification [510(k)] Process Overview, New Policies and Pilots

FDLI Annual Conference

May 2, 2019

Marjorie Shulman, MBA
Director
Office of Regulatory Programs/ 510(k)/513(g) Program Team
Center for Devices and Radiological Health

Overview

SUMMARY OF 510(K) REVIEW PROCESS

- Submission Receipt to Final Recommendation

NEW POLICIES

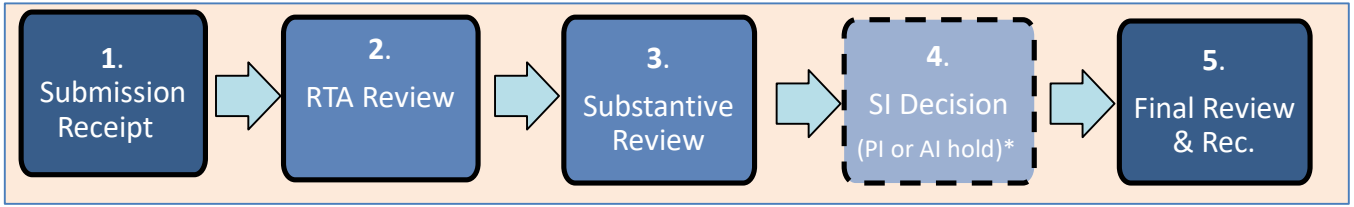
- RTA Addendum
- Day-10 Call
- Down delegation of SE sign-off
- First Round NSE
- Benefit Risk Assessment
- Least Burdensome Flag
- Safety and Performance Based Pathway

PILOTS

- Quality in 510(k) Review
- Special 510(k)

High-Level Process Overview

510(k) Submission Core Process

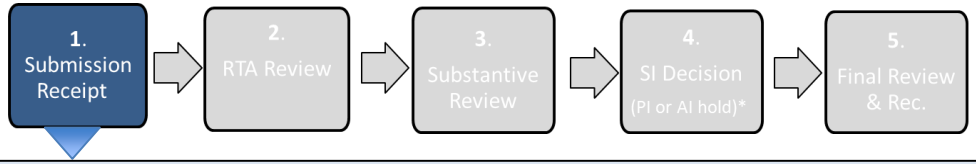


Sub-Processes

- Bundling
- Withdrawal
- Missed MDUFA
- Deletion
- Appeal
- Corrected SE
- Compliance Action 510(k)
- 510(k) Amendments (nine types)

*PI = Proceed interactively, AI = Additional

Submission Receipt

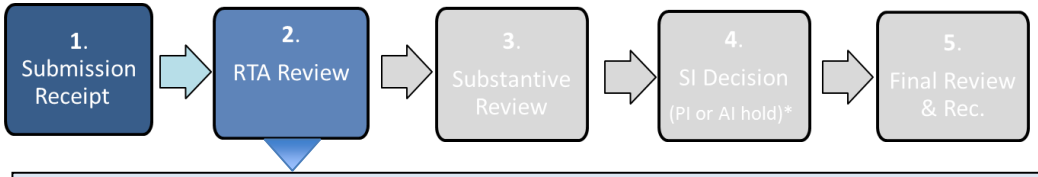


Document Control Center (DCC) receives and processes all 510(k) submissions, supplements and amendments.

- 510(k) submissions are given a submission ID upon receipt.
- Submission ID starts with the letter 'K' and contains six numbers. example, K18####
- DCC checks for appropriate eCopy and user fee
- If there are issues, submission is put on hold
- If a response is not received within 180 calendar days the submission is deleted
- If there are no issues, submission is assigned to a Division of Health Technology

- eCopy: eCopy Program for Medical Device Submissions, 2015
- 510(k) User Fees: User Fees and Refunds for Premarket Notification Submissions (510(k))s

Refuse to Accept (RTA) Review



Administrative quality check that occurs within the first **fifteen (15) days** of a 510(k) submission review. This phase is used to assess the administrative completeness or acceptability of a submission prior to the substantive review.

- Lead Reviewer (LR) assess appropriateness of review track. Converts when appropriate.
- LR can work interactively with the submitter to obtain additional information
- If a high-level NSE is identified RTA review (**RTAS**) is skipped & proceeds to Substantive Review
- LR provides RTA recommendation with subsequent concurrence from designated authority
- Final RTA recommendation sent to submitter by **Day 15**.

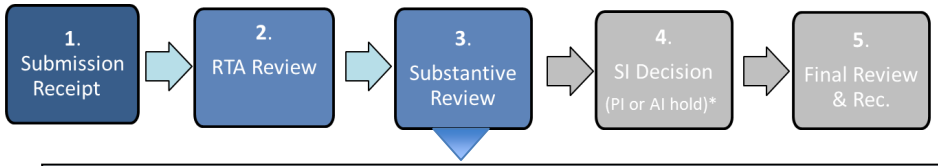
Acceptable

- **(RTAA)** LR proceeds to substantive review

Unacceptable

- **(RTA1)** Submission is placed on hold. If response is not received within 180 calendar days, submission is deleted.

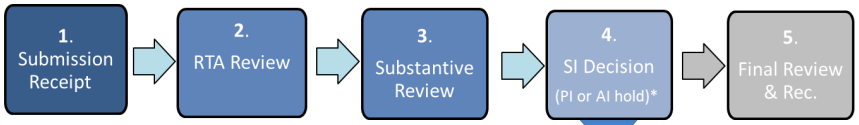
Substantive Review



LR reviews the submission in detail and may interact with the submitter to obtain additional information to help determine whether a new device is substantially equivalent to a predicate device.

- LR downloads the SMART Template Memo (SMART memo) and documents review
- LR decides whether consultation with SME(s) is needed. If so, LR seeks input within the first three (3) weeks of substantive review.
- LR may work interactively with the submitter to address clarification questions.
- LR provides a reasonable timeframe for the submitter to respond depending on the information being requested. (1-2 days for minor questions, 7-10 days for significant question.)
- Substantive Interaction (SI) decision or final decision by **Day 60 for Traditional & Abbreviated** and target **Day 20 for Specials**.

Substantive Interaction (SI) Decision



By Day 60, LR decides whether to Proceed Interactively (PI) or Issue an Additional Information (AI) Letter.

PI

(*via email and/or phone call***)**

- Address questions that can be resolved quickly
- Response timeframe ranges from two to seven (2-7) calendar days
- submitter can negotiate response timeframe w/Lead Reviewer

- submitter's response sent directly to Lead Reviewer.

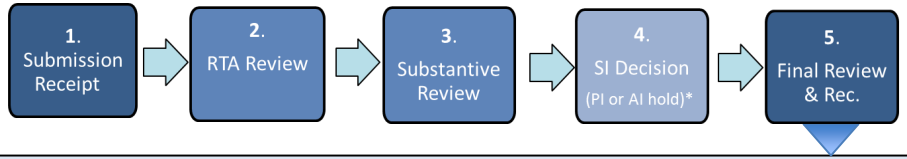
OR

AI Letter

- To address questions that cannot be adequately resolved interactively
- To address complex questions that cannot be resolved quickly
- Submitter is granted 180 days to respond (late submissions are deleted.)

- submitter's response sent as supplement to original 510(k) via DCC.

Final Review & Recommendation



Final review occurs after the SI decision and is a continuation or completion of the substantive review until a final decision is reached. If the submission was placed on hold, FDA clock resumes upon receipt of response to an AI letter.

- LR checks whether the submitter provided a complete response to all the deficiencies within the first five (5) days of supplement
- When necessary, LR resolves remaining questions and deficiencies interactively.
- LR provides a final recommendation for Traditional 510(k) and Abbreviated 510(k) submissions by **Day 90** and **Day 30** for Specials.
- Recommendation and review package are reviewed by DHT and OHT designated authorities for concurrence before letter is issued.
- After appropriate levels of concurrence, the recommendation (SE or NSE)* letter is issued to the submitter.

*SE = substantially equivalent
NSE = Not substantially equivalent

TPLC Key:
Branch = Division of Health Technology (DHT)
Division level = Office of Health Technology (OHT)

510(k) Program – Total Time to Decision

TTD = FDA Days + Industry Days

510(k) Process	Current Timeframe (days)	MIV Change? (Y/N)
RTA Review	≤15	N
FDA Review	≤90	N
Substantive Interaction (SI) Decision	≤60	N
Total Time to Decision (TTD)	≤124 (FY 2017)	Y

MDUFA* IV (M4) TTD Goal

Fiscal Year	2018**	2019**	2020	2021	2022
M4 TTD Goal	124	120	116	112	108

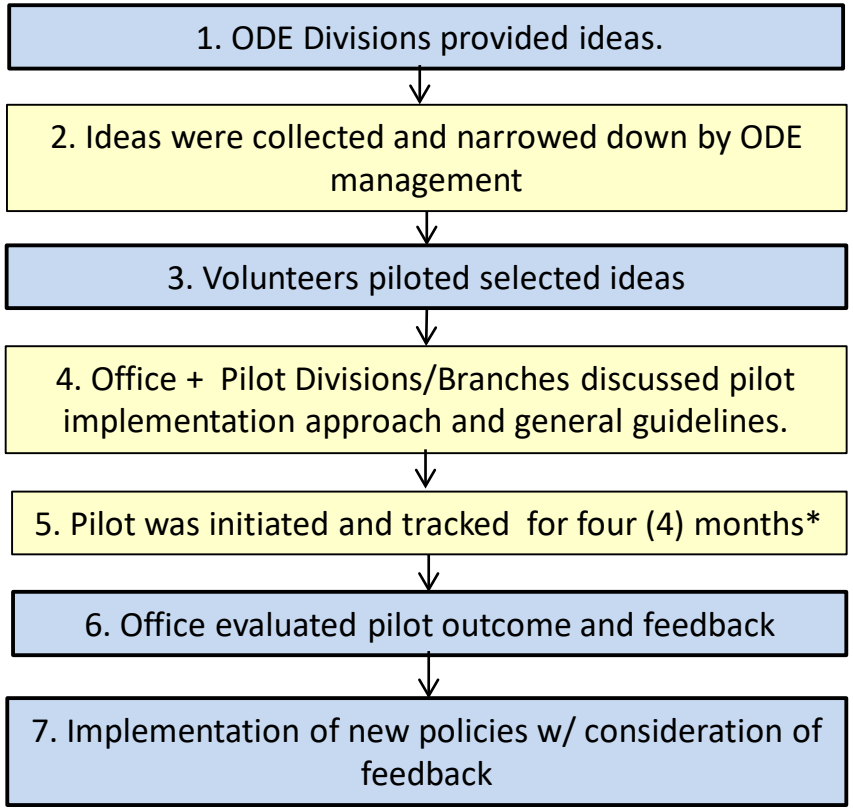
Note: Decrease in TTD performance goal.

*FY18-FY19 receipt cohorts are not complete, data will change

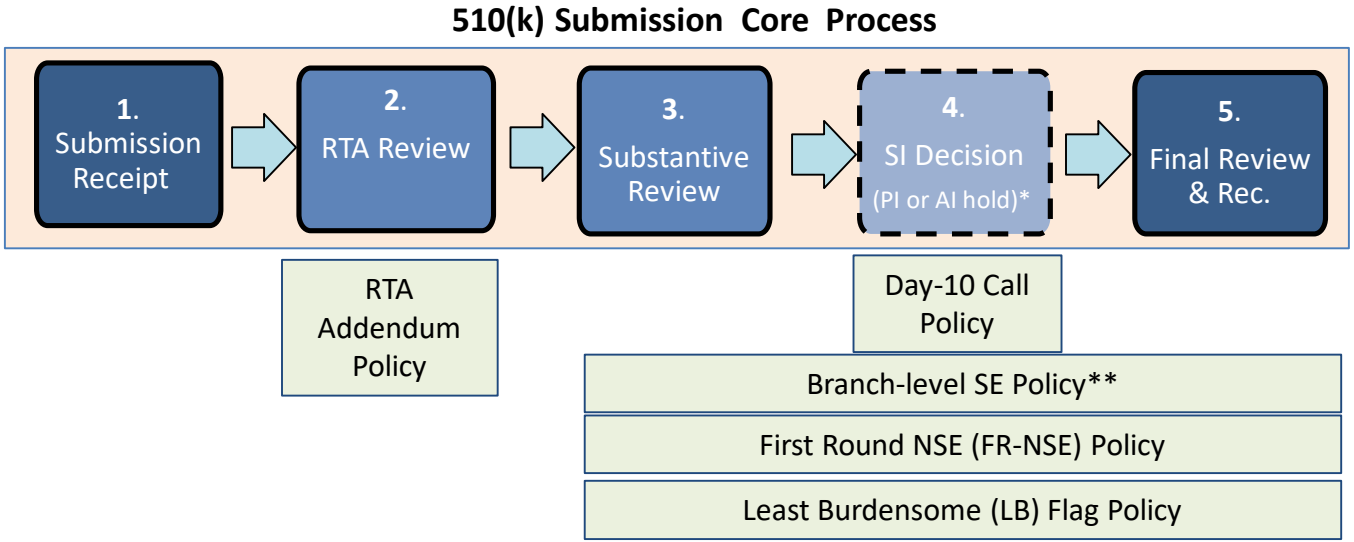
** MDUFA = Medical Device User Fee Agreement

Background

New policies based on suggestions provided by review staff and feedback from Industry.



New 510(k) Policies



TPLC Key:
Branch = Division of Health Technology (DHT)
Division level = Office of Health Technology (OHT)

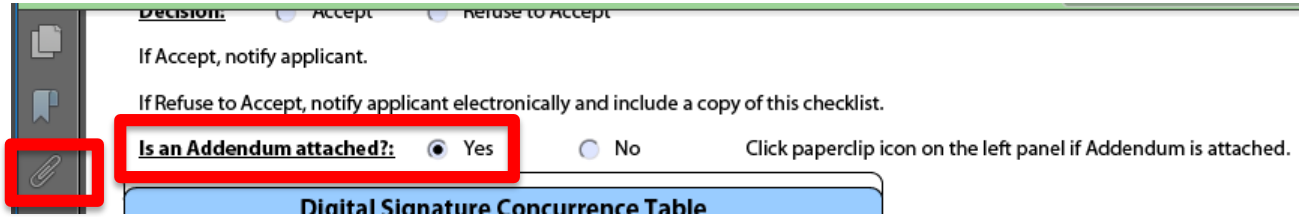
*PI = Proceed interactively, AI = Additional Information
** Previously Branch-level SE pilot

RTA Addendum Policy

What it Is	What it Is Not
• An attachment to the RTA checklist embedded into the PDF • Early notification of "observations" made during the initial RTA review • An opportunity to address issues interactively during substantive review	• Substantive review of the submission • In place of an additional information hold • An official "ask" for additional information • A delay in the RTA review or decision

WHAT IS AN OBSERVATION?

Issue noted during the administrative review that does not determine the acceptability of a submission but would result in a deficiency during substantive review. (Example: Missing a required animal or engineering test.)



Day-10 Call Policy

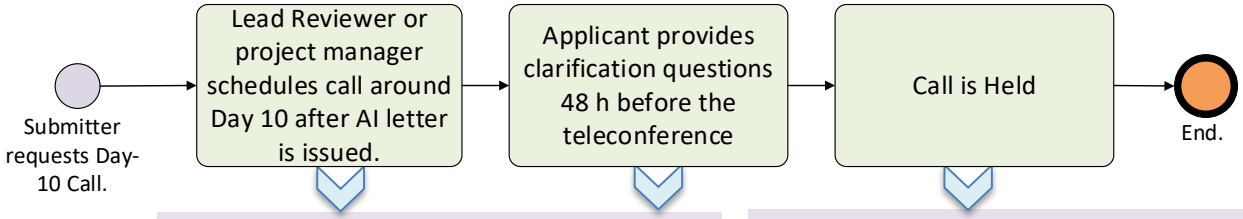
Description: Voluntary call offered by FDA that occurs within ten (10) days after issuance of an AI* letter. The purpose of the call is to address clarification questions pertaining to the deficiencies in the letter.

WHAT IT IS

- Teleconference
- Confirmation that submitter understands deficiencies in the letter
- Can be used to determine whether a Q-Submission is needed.

WHAT IT IS NOT

- Review of additional information provided by submitter
- Discussion of issues unrelated to deficiencies in the AI letter
- A Q-Submission meeting



- LR ensures appropriate participants are included
- Day 10 window is flexible

- The call is not expected to exceed 30 minutes

*AI = Additional Information

Day-10 Call Policy Continued…

- **Day-10 Call Language in 510(k) AINN letter**

FDA is offering a teleconference within 10 days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please send the following information to the contact specified in this email: (1) proposed dates and (2) a list of your clarification questions at least 48 hours before the teleconference. We would like to emphasize that the purpose of the teleconference is to address specific clarification questions. This teleconference is not intended for review of new information or your approach to address the deficiencies. If you would like a meeting or teleconference to discuss your planned approach for responding to the deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: The Pre-Submission Program and Meetings with FDA Staff at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

SE Final Concurrence at the Branch Level Policy

Description: Straight forward SE letters are signed out by the branch chief. This approach reduces time spent waiting for Division Director's review and concurrence.

When Can a Branch Chief provide final concurrence on an SE recommendation?

- The review team has reviewed similar devices with similar regulatory requirements
- Branch has extensive knowledge of the product area
- The device or submission is not complex from a regulatory or performance data standpoint (Example: Clinical data needed for a change in indication and/or technology might not be appropriate for Branch-level SE concurrence.)
- SE recommendation is not controversial and/or does not have potential to be controversial. (Example: A 510(k) claiming equivalence to a recalled device might not be appropriate.)

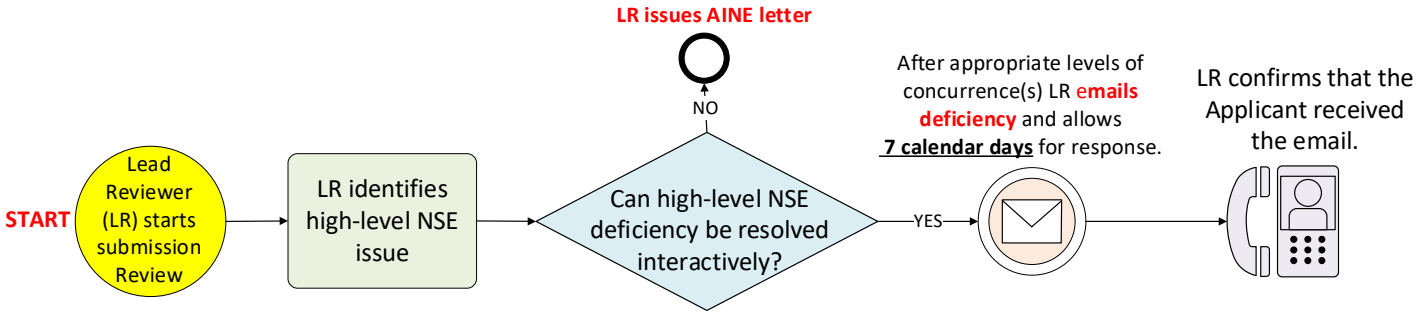
TPLC Key: Branch Chief = Division of Health Technology Assistant Director (DHT AD) OHT = Office of Health Technology

First-Round (FR-NSE) Policy

Description: A submission does not have to go on hold before a high level NSE recommendation is issued as long as the submitter has an opportunity to resolve the NSE issue interactively.

High-level NSE reasons:

- No valid predicate
- New intended use
- Different technological characteristics that raise different questions of safety and effectiveness when compared to the predicate.



NOTE: Potential NSE letter (AINE) can still be issued if FR-NSE was attempted and the deficiency cannot be adequately resolved interactively.

First-Round NSE (FR-NSE) Policy

Reviewing Response to FR-NSE Email:

- **Adequate response.** If the interactive response is adequate, the LR continues with substantive review.
- **Interactive review.** The LR works interactively to address minor clarification questions to the response when needed**.**
- **Inadequate response.** If the response is not adequate, the LR, with appropriate levels of concurrences, issues an NSE letter within 30 calendar days.
- **Additional information letter (AINN).** An AINN letter can still be issued for non-NSE issues that cannot be adequately resolved interactively.

First-Round (FR-NSE) Policy continued…

Approach for FR-NSE based on submitter's Responsiveness with concurrence from Branch Chief

Table 1: Approach on FR-NSE based on submitter's Responsiveness	
Responsive submitter who cannot meet timeframe	If the submitter responds, they must confirm whether a complete response can be provided within the timeframe specified in the email. If a complete response cannot be provided, and submitter and LR do not agree upon an alternative date, an **NSE letter is issued within 30 calendar days from email issuance.**
Responsive submitter who meets timeframe	LR reviews response and addresses minor clarification questions when appropriate.
Non-responsive submitter	If the submitter does not provide any response to the original email or voicemail, an NSE letter is issued **no sooner than one day after the response was due.**
Late Responder	It is at the review team's discretion to determine whether there is sufficient time remaining to address a late response. If there is not sufficient time, **an NSE letter is issued within 30 calendar days after email issuance.** The LR is not obligated to review a late response if there is not sufficient time for an adequate review.

TPLC Key: Branch Chief = DHT AD

Least Burdensome (LB) Flag Policy

Description: The least burdensome flag is an opportunity for a submitter to request an informal review by upper management because they believe the FDA's request is not least burdensome or that they are being held to an inappropriate review standard.

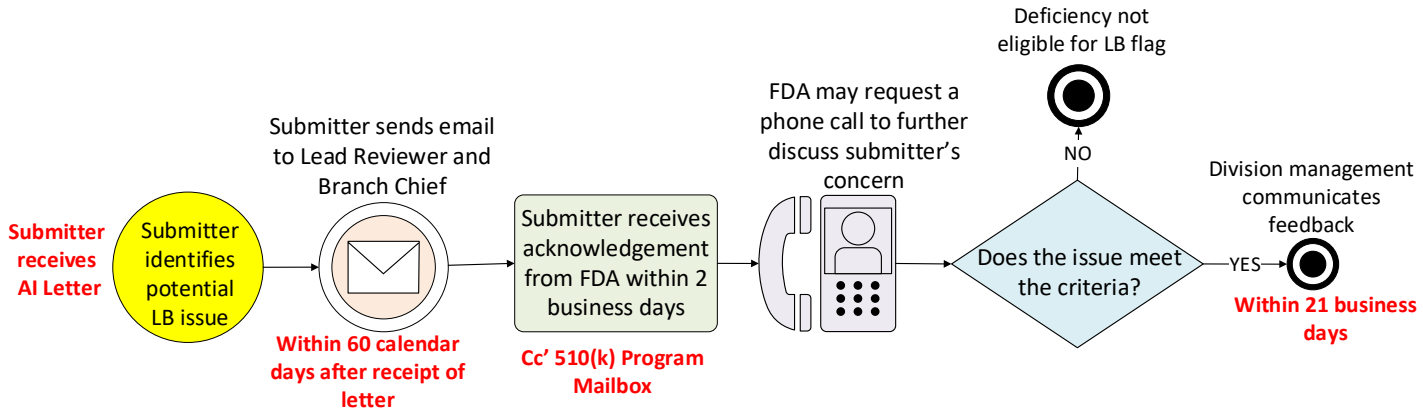
Definition of Least Burdensome

The minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time.

The Least Burdensome Provisions: Concept and Principles Guidance for Industry and FDA (February, 2019)

Least Burdensome (LB) Flag Policy

What it Is	What it Is Not
• Opportunity to address LB discrepancies in an AI letter • Opportunity for submitter to address situations when they feel they are being held to a different standard	• An Appeal Meeting • Change to 180 Response deadline

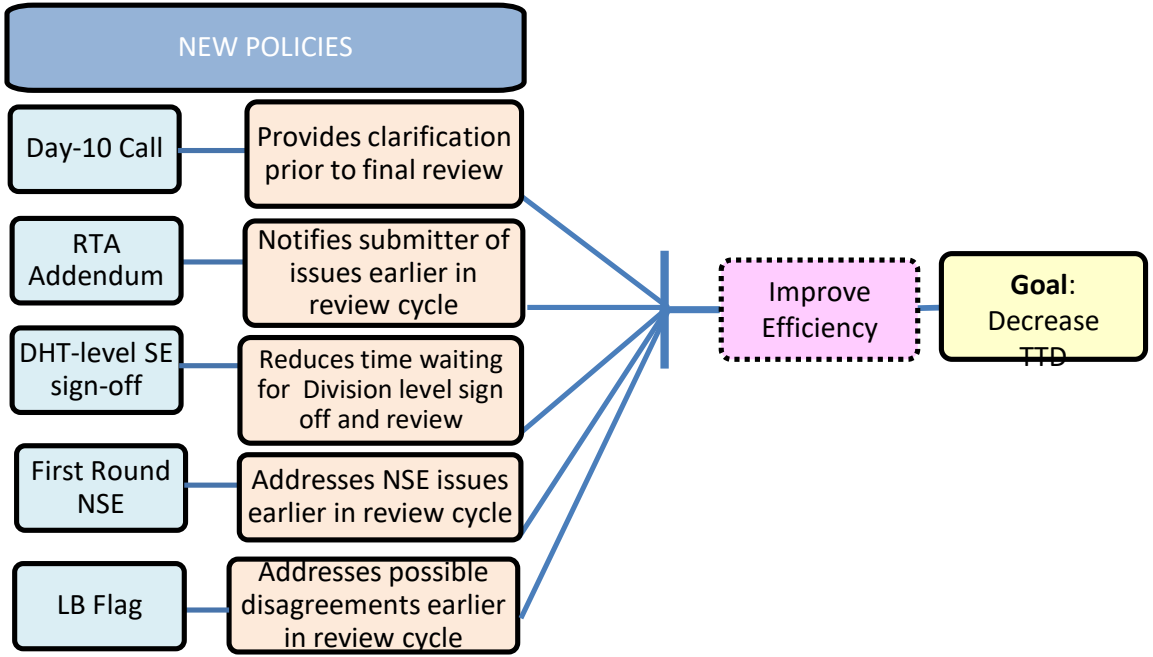


Least Burdensome (LB) Flag Policy continued

- **Pre-requisite**
  - Submitter initiates discussion with branch management via email, Day-10 call or Q-sub

- **Requirements**
  - LB flag is limited to two topic areas (e.g. biocompatibility, sterility, reprocessing, software, etc.)
  - Submitter contacts 510k_Program@fda.hhs.gov if they seek to address additional topic areas.
  - Flag is thrown within 60 calendar days post receipt of AI letter
  - If Division management determines that the aforementioned requirements are met, the submitter provides **a brief email summarizing the issue, discussions and path forward**

Goal of New Policies



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Benefit-Risk Assessment Policy

Description: 510(k) Benefit Risk Guidance outlines the policy for evaluating substantial equivalence in a 510(k) when the benefit-risk profile of a new device is different from that of the predicate device based on performance data.

510(k) B-R Guidance:

- Serves as **an aid** for evaluating benefit-risk factors to determine SE in a 510(k)
- This guidance **does not change the 510(k) premarket review standard** or create extra burden on a submitter to provide additional performance data from what has traditionally been expected for 510(k)s.
- Provide guidance **specifically for situations when the benefit-risk profile of a new device is different from that of the predicate device**
- Provides **additional clarification** on factors that FDA takes into consideration when evaluating the benefit-risk profile of a new device when compared to a predicate device
- Improves the **predictability, consistency, and transparency** of the 510(k) premarket review process

Benefit-Risk Assessment Policy Continued

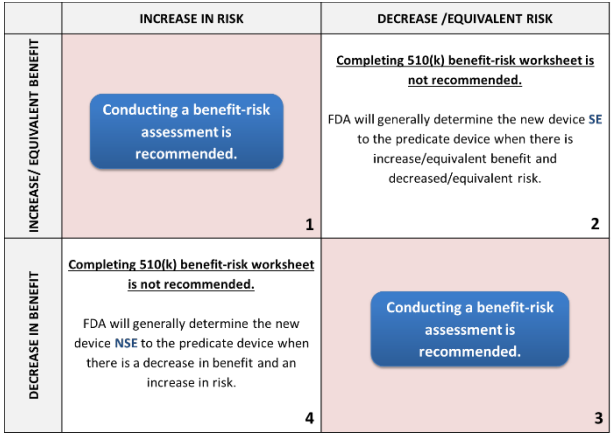
Table serves as a guide for when benefit-risk assessment is recommended in a 510(k). This table should be used with the guiding principles provided in the rest of the guidance.

	INCREASE IN RISK	DECREASE /EQUIVALENT RISK
INCREASE/ EQUIVALENT BENEFIT	**Conducting a benefit-risk assessment is recommended.** FDA evaluates the nature of the increased risk and considers whether additional measures may help to mitigate the increased risk**. FDA will generally not deem a new device SE to a predicate when the increased risk cannot be mitigated and is not accompanied by an increase in benefit**. **1**	**Conducting a benefit-risk assessment is likely not recommended to determine whether the new device is "as safe and effective" as the predicate device.** FDA will generally determine the new device **SE** to the predicate device when there is increase/equivalent benefit and decreased/equivalent risk. **2**
DECREASE IN BENEFIT	**Conducting a benefit-risk assessment is likely not recommended to determine whether the new device is "as safe and effective" as the predicate device.** FDA will generally determine the new device **NSE** to the predicate device when there is a decrease in benefit and an increase in risk. **4**	**Conducting a benefit-risk assessment is recommended.** If the aggregate benefit of a new device is decreased in and the risk level is decreased, FDA may determine the new device to be SE if the differences do not impact whether the new device is at least "as safe and effective". **However, if there is a decrease in benefit without a decrease in risk, FDA would likely find a device NSE to the predicate especially if the B-R assessment confirms that the new device is not "as safe and effective" as the predicate device**. **3**

Who Performs a Benefit Risk Assessment?

- **Submitter**:
  - If the benefit-risk profile comparison falls in quadrants 1 or 3, the submitter can include a benefit-risk assessment in a 510(k) submission, but it is not required.

- **FDA**:
  - If the benefit-risk profile comparison falls in quadrants 1 or 3, the Lead Reviewer performs a benefit risk assessment.
  - If there is not sufficient information in the submission, the Lead Reviewer can request summary benefit-risk information from the submitter to help complete the benefit-risk assessment.



Safety and Performance Based Pathway

Current Abbreviated 510(k)

The Abbreviated 510(k) submission program relies on the use of guidance documents, special controls, and FDA-recognized consensus standards to facilitate 510(k) review.

Safety and Performance Based Pathway Policy

- Optional program that expands on the concept of the Abbreviated 510(k) for certain well understood device types
- Supports least burdensome provisions
- Robust requirements for Abbreviated 510(k) to support SE are still applicable however, using direct predicate comparison testing to support a finding of SE for some of the performance characteristics is not required

Link to Guidance

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195.pdf

Safety and Performance Based Pathway continued

The FDA expects to begin implementation of this pathway once the first device types and applicable performance criteria have been identified. Once the FDA begins to implement this pathway, a medical device manufacturer will be able to meet FDA-identified performance criteria to demonstrate that its device is as safe and effective as a predicate device.

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195.pdf

Safety and Performance Based Pathway continued

Eligibility Criteria

- The predicate is within the scope of the eligible device types
- The new device meets all the FDA-identified performance criteria
- Appropriate when the new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate
- The performance criteria align with the performance of one or more legally marketed devices of the same type as the new device; and

Things to Note

- Industry may suggest device types for consideration
- FDA expects to begin implementation of this pathway once the first device types and applicable performance criteria have been identified
- FDA intends to maintain a list of device types as well as the testing methods recommended in the guidances where feasible

Pilots

Pilot Webpage

Special 510(k) Pilot

Description: The purpose of the Special 510(k) Program pilot is to expand on the types of changes eligible for the program to improve the efficiency of 510(k) review.

Existing Special 510(k) policy	Change of Policy in Pilot?
1. The proposed change is made and submitted by the manufacturer authorized to market the existing device. (i.e. the predicate should be the manufacturer's own device.)	**No.** (Note: Special 510(k) leverages information already submitted to FDA and existing design controls procedures.)
2. Change does not affect the indications for use/Intended Use.	**Yes.** To support the differences between the new and the predicate device the following apply: • If performance date is required, **summary level data and/or risk analysis** should be sufficient to support the change and SE. • **Well-established** methods are available to evaluate the change **OR** • Performance data is not required to support the change.
3. Differences in technological characteristics does no raise different questions of safety and effectiveness.	

Special 510(k) Pilot Policy continued…

What is a well- established method?

- Those used in a previously cleared 510(k)
- Methods in an FDA-recognized consensus standard
- Widely available and accepted methods, or those in another premarket submission

- All methods used in subject 510(k) should be well-established
- If there is not a well-established method, the FDA intends to convert the submission to a Traditional

Special 510(k) Program Pilot

Eligibility factors:

1. The proposed change is made and submitted by the manufacturer authorized to market the existing device
2. Change can be due to labeling (IFU) or technology
3. Performance data are unnecessary
4. If performance data is necessary, **well-established methods** are available to evaluate the change. Example of well-established methods includes recognized consensus standard, previously cleared test methods and widely available/accepted methods
5. All performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format.

If there is not a well-established method, FDA intends to convert the submission to a Traditional

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm618561.htm

Quality in 510(k) Review Pilot

Description: The purpose of the Quik Review Program pilot is to determine whether use of the FDA's free eSubmitter software will produce well-organized submissions that can be reviewed more efficiently to help promote timely access to safe, effective, and high-quality medical devices.

- **Eligibility:**
  - Specific product codes
  - Required use of eSubmitter to construct 510(k) submission
  - Not a combination product
  - Traditional and Abbreviated 510(k)s (no Specials)
- **No RTA review**
- **Interactive review**
- **Final decision expected by FDA Day 60**
- **If ineligible, submission is converted to 90 FDA Day timeframe**
- **Complex issues could render the file ineligible for the pilot**

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm618561.htm

Current Resources

Guidance Documents

- Deciding When to Submit a 510(k) for a Change to an Existing Device, Draft Guidance - August 8, 2016
- Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s)
- Refuse to Accept Policy for 510(k)s, August 4, 2015
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], July 28, 2014
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, May 20, 1998
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, October 15, 2012
- Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA
- Procedures for Class II Device Exemptions from Premarket Notification, February 19, 1998
- Bundling Multiple Devices or Multiple Indications in a Single Submission, November 26, 2013
- The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles, October 4, 2002
- Medical Device Classification Product Codes Guidance, April 11, 2013

Questions? Contact 510k_Program@fda.hhs.gov

Thank-you!

Evolving 510(k) Program and De Novo Process

Nicole Taylor Smith, Vice President, Global Regulatory Policy, Medtronic

Industry Considerations

- Proposed rule aims to enhance regulatory clarity and predictability by providing a framework for clear expectations and processes for De Novo classification.
- De Novo - Classification process
- Confidentiality and Disclosure
- Inspections and Clinical Trials
- Labeling
- Advisory Committees

Evolving 510(k) Program and De Novo Process

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