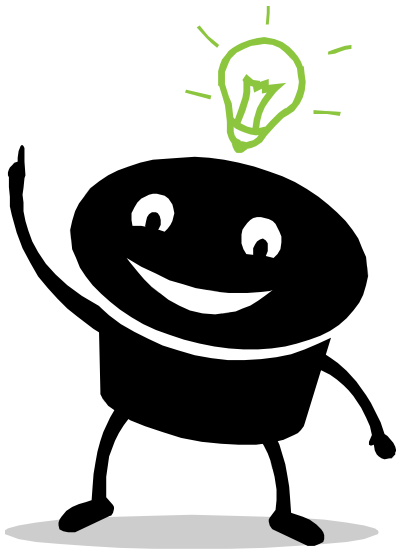
The 510(k) Process
"What You Need to Know"

FDA Small Business
Regulatory Education for Industry (REdI)
Burlingame, CA
June 16, 2014

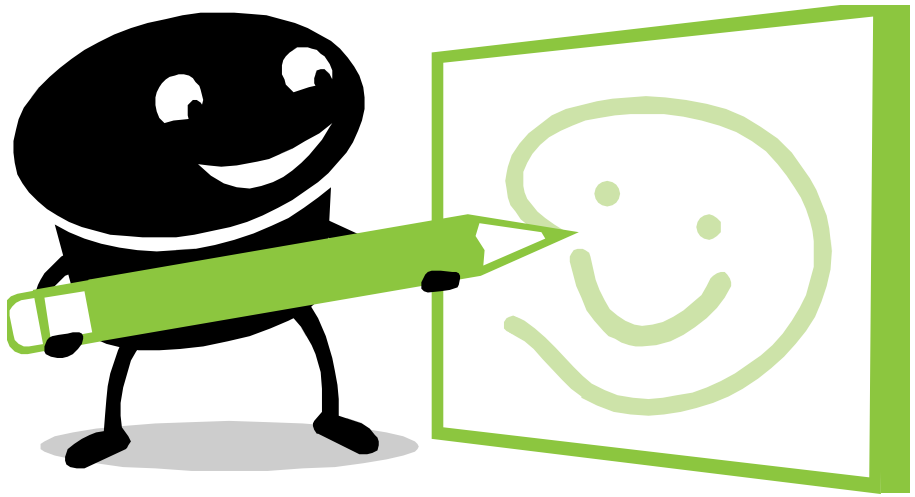
LCDR Kimberly Piermatteo, MHA, CPH
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

A Premarket Notification [510(k)] is one of the major processes in device marketing.



When I say 510(k), you may feel like this…

Hopefully, by the end of this presentation, you will feel more like this…



Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

Presentation Outline

- **Device Classification As It Relates to 510(k)s**
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

Device Classification As It Relates to 510(k)s

- Class I = Low Risk Devices
- **Class II = Moderate Risk Devices**
  - ***Most, not all, Class II devices require a premarket notification or 510(k).***
- Class III = High Risk Devices

**NOTE: All classes are subject to general controls such as labeling and Good Manufacturing Practices (unless exempt).*

Product Codes

- Three letter codes.
- Used by FDA to identify and track similar medical devices.
- Used by applicants to search for a predicate device(s).
- Found on all 510(k) clearance letters.

References:

- Guidance Medical Device Classification Product Codes
- Product Classification Database

Product Classification Example

Device	System, Test, Blood Glucose, Over The Counter
Regulation Description	Glucose test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	NBW
Premarket Review	Office of In Vitro Diagnostics and Radiological Health (OIR)
Submission Type	510(k)
Regulation Number	862.1345
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

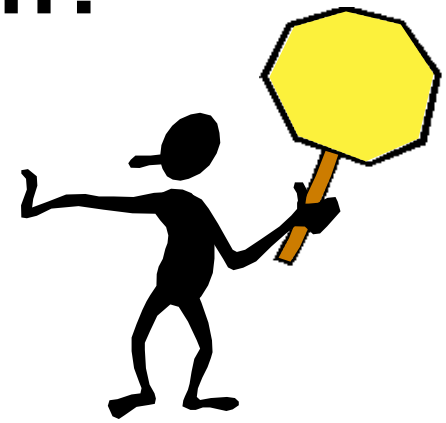
- CLSI C30-A2 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities
- CLSI H04-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens
- IEEE/ISO 11073-10417 First edition 2010-05-01 Health informatics - Personal health device communication - Part 10417: Device specialization - Glucose meter

Guidance Document

- Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems

Third Party Review	Not Third Party Eligible

What do you do if you cannot determine the appropriate device classification?



513(g) Program

513(g) Important Notes

- There is a 513(g) User Fee. FY2014 it is $3,490 ($1,745 for a small business).

- FDA responses to requests for information about the regulatory requirements applicable to a particular device DO NOT constitute FDA clearance or approval for distribution of that particular device in the U.S.

References:

- Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act
- Guidance for Industry and Food and Drug Administration Staff - User Fees for 513(g) Requests for Information
- Medical Device User Fee Rates for Fiscal Year 2014

Presentation Outline

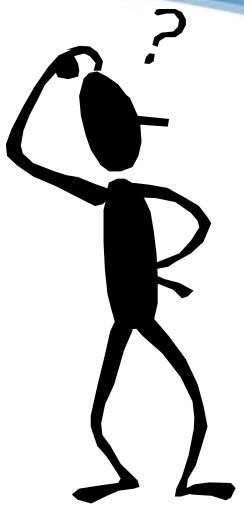
- Device Classification As It Relates to 510(k)s
- **Overview of 510(k) Program**
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

What is a 510(k) Vs. What is Not a 510(k)

- Premarket Notification
- Section 510(k) of Federal FD&C Act
- 21 CFR 807 Subpart E
- It is a marketing clearance application
- 510(k)s are “cleared”
- Allows FDA to determine Substantial Equivalence (SE)

- A Form
- Establishment Registration
- Device Listing
- Premarket Approval (PMA)

When is a 510(k) Required?



- Introducing a device to the market for the first time.
- Changing the indications for use of a previously cleared device.
- Making significant modification(s) to a previously cleared device.

Types of 510(k) Submissions

Traditional 510(k)

Abbreviated 510(k)

Special 510(k)

Traditional 510(k)

- Required elements (21 CFR 807.87).
- Relies on the demonstration of substantial equivalence.
- **The Traditional 510(k) method can be used under any circumstance.** The Abbreviated 510(k) and Special 510(k) methods can only be used if certain criteria are met.

Reference:

- How to Prepare A Traditional 510(k)

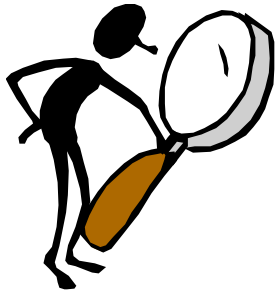
Abbreviated 510(k)

- Relies on the use of guidance documents, special controls, and recognized standards.
- Required elements (21 CFR 807.87).
- Under certain conditions, sponsors may not need to submit test data in an abbreviated 510(k).
- Reference: How to Prepare An Abbreviated 510(k)

Special 510(k)

- Device modification to manufacturer's own legally marketed device.
- Modification does NOT affect the intended use or fundamental scientific technology.
- Required elements (21 CFR 807.87).
- No data is evaluated by FDA.
- Reference: How to Prepare A Special 510(k)

What is a Predicate Device?



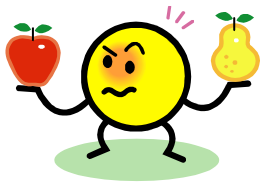
- A legally marketed device, previously cleared through the 510(k) process *mainly*, that is used for comparison to a new device for the purpose of determining substantial equivalence (21 CFR 807.92(a)(3)).

Reference:

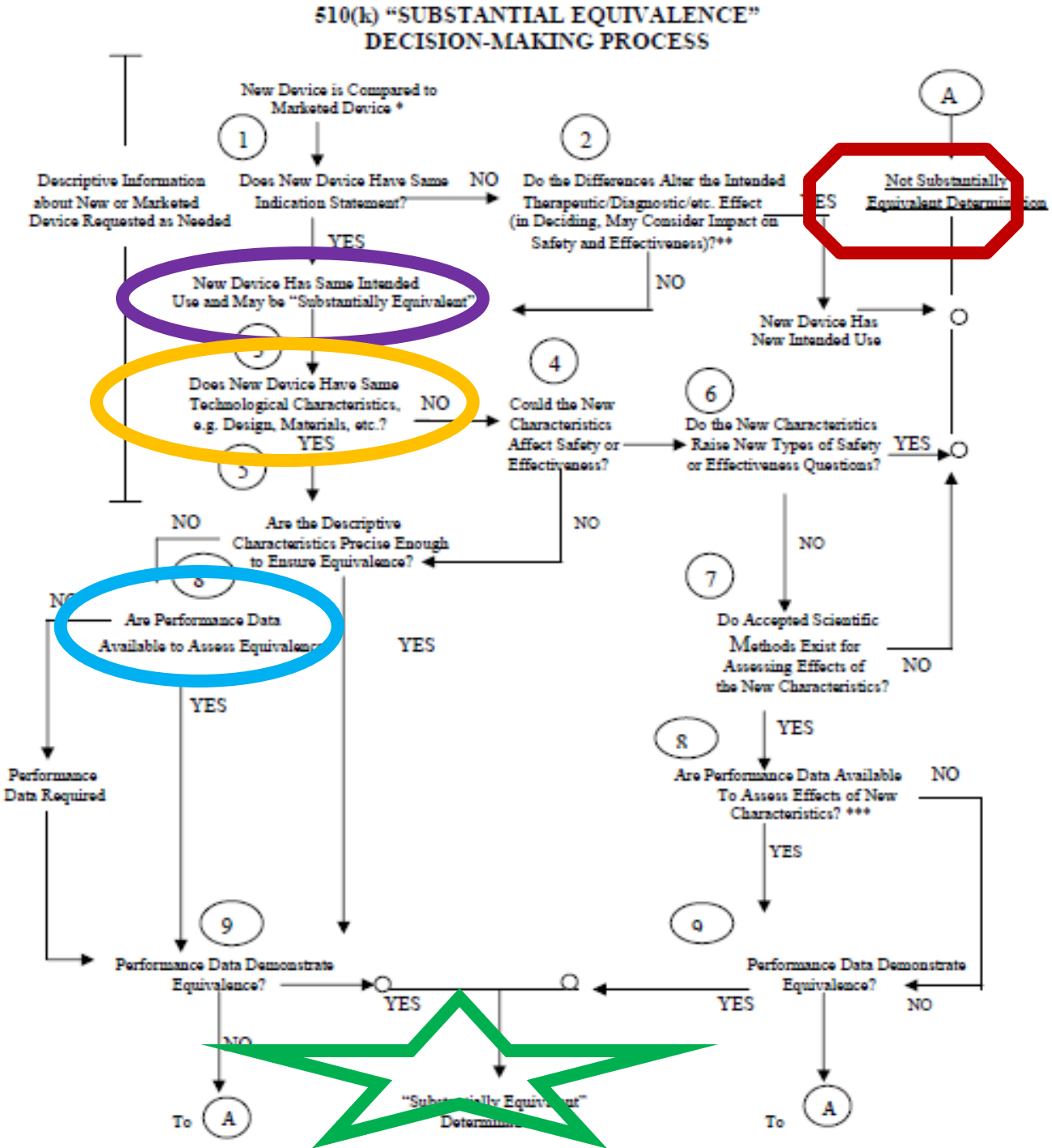
- How To Find A Predicate Device

What is Substantial Equivalence (SE)?

- Demonstration that a new device, as compared to a predicate device, has…
  - the same intended use,
  - the same technological characteristics, **or**
  - differences that don't raise new questions regarding safety and effectiveness.



510(k) Decision-Making Flow Chart



Establishing Substantial Equivalence

Three Important Questions

1. Does the new device have the same indications for use?
2. Does the new device have the same technological characteristics?
3. Are performance data available to assess equivalence?

Reference:

- Guidance on the CDRH Premarket Notification Review Program (K86-3)

What do you do if…

You have a low or moderate risk device with no identifiable predicate devices?

De Novo

Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- **Content of a 510(k)**
- 510(k) Submission Process
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

Content of a 510(k)

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Summary or 510(k) Statement
- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement
- Declarations of Conformity and Guidance Documents
- Executive Summary
- Device Description
- Substantial Equivalence Discussion
- Proposed Labeling
- Sterilization and Shelf Life
- Biocompatibility
- Software
- Electromagnetic Compatibility and Electrical Safety
- Performance Testing – Bench
- Performance Testing – Animal
- Performance Testing – Clinical
- Other

Content of a 510(k)

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- **Indications for Use Statement**
- **510(k) Summary** or 510(k) Statement
- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement
- **Declarations of Conformity and Guidance Documents**
- Executive Summary
- **Device Description**
- **Substantial Equivalence Discussion**
- **Proposed Labeling**
- **Sterilization and Shelf Life**
- **Biocompatibility**
- **Software**
- **Electromagnetic Compatibility and Electrical Safety**
- **Performance Testing – Bench**
- **Performance Testing – Animal**
- **Performance Testing – Clinical**
- Other

Intended Use and Indications for Use

- **Intended Use:** General purpose of the device or its most basic function, and encompasses the indications for use.
  - **Indications for Use:** As defined in 21 CFR 814.20(b)(3)(i), a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
- Must be consistent throughout your 510(k), including the indications for use statement, proposed labeling, etc.
- Recommended Format for Indications for Use Statement (Form FDA 3881).
  - Identify prescription use and/or over-the-counter use.

510(k) Summary

- High level discussion of the content within the 510(k).
- Must include elements in 21 CFR 807.92.
- Must include sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

FDA Recognized Consensus Standards (Declarations of Conformity)

- Voluntary program.
- Used to simplify and streamline the 510(k) review process.
- Sponsors can only declare conformance to FDA recognized consensus standards.
- Must document extent of conformance in 510(k) application (Form FDA 3654 - Standards Data Report for 510(K)s).

References:

- Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards
- Frequently Asked Questions on Recognition of Consensus Standards
- Recognized Consensus Standards Database
- Standards Data Form for 510(k)s

FDA Guidance Documents

- Represents FDA's current thinking on a topic.
- May be device specific or general.
- Does not create or confer any rights for or on any person and does not operate to bind FDA or the public.
- Alternative approaches may be used if the approach satisfies the requirements of the applicable statutes and regulations.

Reference:

- FDA Guidance Document Database

Recap: Product Classification Example

Device	System, Test, Blood Glucose, Over The Counter
Regulation Description	Glucose test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	NBW
Premarket Review	Office of In Vitro Diagnostics and Radiological Health (OIR)
Submission Type	510(k)
Regulation Number	862.1345
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- CLSI C30-A2 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities
- CLSI H04-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens
- IEEE/ISO 11073-10417 First edition 2010-05-01 Health informatics - Personal health device communication - Part 10417: Device specialization - Glucose meter

Guidance Document

- Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems

Third Party Review	Not Third Party Eligible

Device Description

Include:

- Performance specifications;
- Device design requirements;
- Identify all models, accessories, and components;
- Diagrams, dimensions, tolerances, and/or schematics;
- List all patient contacting components and their respective materials.

Substantial Equivalence Discussion

- Substantial Equivalence is defined in section 513(i) of the FD&C Act.
- Utilize 510(k) Decision-Making Flowchart.
- 510(k) review standard is comparative (i.e. new device compared to predicate device).
  - Multiple predicate devices are ok under certain circumstances.
  - Split predicates are inconsistent with 510(k) regulatory standard.

Labeling

- Comply with Device Labeling Requirements (21 CFR 801).
- Copies of all proposed labels, labeling, package inserts, service manuals, instructions for use, advertising and/or promotional materials.
- The directions for use should include a specific intended use statement and any warnings, contraindications, or limitations.
- Labeling submitted should be **final draft**.
- Copies of labeling for the predicate device(s) is recommended.

Reference:

– Introduction to Medical Device Labeling

Sterilization/Shelf Life

- Sterilization is defined as a validated process used to render a product free of all forms of viable microorganisms.
- Labeling must provide adequate instructions for reusable devices.
- Shelf Life is device specific and should be supported by appropriate bench tests and/or sterilization (packaging) validation.
  - Real-time or accelerated aging testing.

References:

- Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (Intended to supersede K90-1)
- Liquid Chemical Sterilization
- Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants

Biocompatibility

- To determine the potential toxicity resulting from contact of the component materials of the device with the body.
- Appropriate tests are determined based on the nature, degree, frequency and duration of its exposure to the body.
- The final product should be tested (this includes after sterilization, if applicable).
- Include: test methods, acceptance criteria and test results for review.

References:

- Use of ISO 10993 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing"
- 510(k) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration
- Special Considerations – Biocompatibility
- Draft Guidance (April 23, 2013) : Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Software

- Software development and validation should be based on the level of risk of the software.
- The extent of documentation that we recommend you submit is proportional to the Level of Concern associated with the device.
- Level of Concern (Major, Moderate or Minor).

References:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Final Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications

Electromagnetic Compatibility (EMC)/ Electrical Safety

- Electrical Safety (e.g. electric shock, burns, or electrical interference, leakage current, etc.) and Electromagnetic Compatibility (EMC).

- Recognized Consensus Standards IEC 60601-1-2 Medical Electrical Equipment or an equivalent method.

References:

- Electromagnetic Compatibility (EMC)
- Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
- Wireless Medical Devices

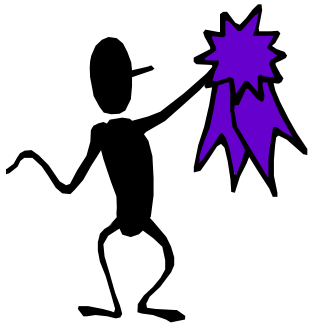
Performance Testing

- Bench, Animal, or Clinical.
- Necessary performance tests depend on the complexity of the device and its intended use and indications.
- Consider FDA Guidance Documents.
- Consider comparative testing to demonstrate substantial equivalence.
- Include: test methods, acceptance criteria and test results for review.

Performance Testing - Clinical

- Less than 10% of 510(k)s require clinical data.
- Clinical data may be requested in the following situations:
  1. New or Modified Indications for Use – Same Intended Use
  2. Significant Technological Differences
  3. Non-clinical Testing Methods are Limited or Inappropriate Because of the Indications for Use or Device Technology

Content of a 510(k) – Key Considerations



- Information is complete and organized.
  - Include a table of contents.
  - Use tabs and paginate properly.
  - Utilize tables and graphs appropriately and effectively.
  - Use visual aids whenever possible.
- Clearly identify basic 510(k) requirements (e.g. 510(k) Summary, Indications for Use Form, etc.).
- Be consistent throughout the submission.
- Follow current applicable guidance documents and device specific checklists.
- Keep informed about regulatory changes (e.g. proposed/final regulations).

Pre-Sub for a 510(k)

- Final Guidance: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff.
- Obtain FDA feedback prior to submission of your 510(k).
- Submit a formal written request to the FDA.
- Request either a formal written response, meeting, or teleconference to address their concerns, questions, etc.
- Subject to eCopy requirements.

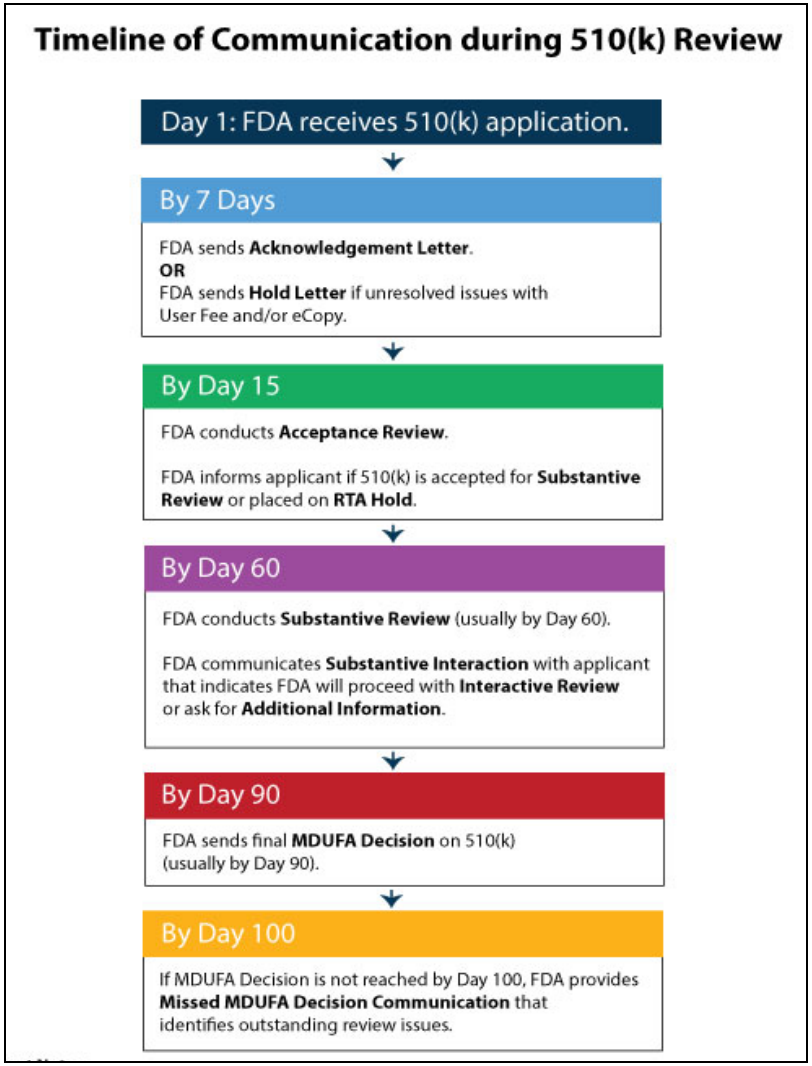
References:

- Final Guidance [Pre-Sub for a 510(k) - See Appendix C]
- CDRH Learn Webinar - Pre-Submissions and Meetings with FDA Staff [2/28/2014]

Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- **510(k) Submission Process**
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

510(k) Submission Process

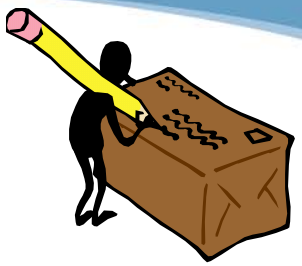


Important Notes:

- Days are Calendar Days.
- The timeline is based on the MDUFA III Performance Goals.
- This timeline has been simplified.

References:

- 510(k) Submission Process
- Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff



Submission to FDA

- You must submit **two copies** of your 510(k).
- One of your two copies must be submitted in an electronic format (i.e. eCopy).
- FDA does NOT return the 510(k) submission after review.
- Address:

  Food and Drug Administration
  Center for Devices and Radiological Health
  Document Control Center - WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, Maryland 20993-0002

Reference:

- Addresses for Submissions

eCopy Program

- Requirement for Premarket Submissions – Valid eCopy.
- An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive.
- An eCopy is accompanied by a paper copy of the signed cover letter and the complete paper submission.
- Questions regarding eCopy requirements or responses to eCopy holds should be sent to CDRH-eCopyinfo@fda.hhs.gov.

References:

- Guidance eCopy Program for Medical Device Submissions
- How to Submit an eCopy – Instructional Video

510(k) eSubmission Program

- April 2014, pilot program for 510(k)s submitted in the Cardiac Diagnostics Devices Branch and Peripheral Interventional Devices Branch.
- Uses eSubmitter software.
- 510(k) sponsors of all device types are encouraged to review the user interface and provide feedback via the Federal Register docket.
- CDRH 510(k) eSubmissions Pilot staff: eSubpilot@fda.hhs.gov.

References:

- 510(k) eSubmissions Pilot Program
- CDRH Learn Webinar - 510(k) Electronic Submission Pilot Program [5/5/2014]

Premarket Notification [510(k)] Review Fees

FY2014 Device Review User Fees (U.S. Dollars)		
Submission	Standard Fee	Small Business Fee
510(k)	**$5,170**	**$2,585**

References:

- Premarket Notification [510(k)] Review Fees
- Guidance FY 2014 Medical Device User Fee Small Business Qualification and Certification

510(k) Submission Process

Timeline of Communication during 510(k) Review

Day 1: FDA receives 510(k) application.

↓

By 7 Days

FDA sends **Acknowledgement Letter.**
OR
FDA sends **Hold Letter** if unresolved issues with User Fee and/or eCopy.

↓

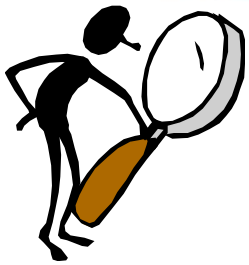
510(k) Submission Process

By Day 15

FDA conducts **Acceptance Review**.

FDA informs applicant if 510(k) is accepted for **Substantive Review** or placed on **RTA Hold**.

Refuse to Accept (RTA) Policy



- Is the 510(k) submission administratively complete for substantive review?
- Early Review – 15 calendar days from receipt.
- Necessary elements and content of a complete 510(k) submission (Refer to RTA Checklist in Guidance).
- FDA clock begins on the date of receipt when the 510(k) is "accepted for review."

Reference:

- Final Guidance Refuse to Accept Policy for 510(k)s

510(k) Submission Process

By Day 60

FDA conducts **Substantive Review** (usually by Day 60).

FDA communicates **Substantive Interaction** with applicant that indicates FDA will proceed with **Interactive Review** or ask for **Additional Information**.

Substantive Review

Substantive Review is conducted by the following:

- Lead Reviewer (e.g. chemical, mechanical, biomedical or electrical engineer, chemist, biologist, nurse consultant)
- Clinical Reviewer
- Statistician
- Specialty Reviewers (e.g. software, biocompatibility, microbiology, chemistry, toxicology, etc.)
- Project Manager
  - Assists with inter-center consults
  - Sets up meetings and teleconferences

Substantive Interaction

FDA Notification that:

1. The 510(k) will not be placed on hold and outstanding deficiencies will be resolved via Interactive Review.
2. The 510(k) is being placed on hold and identification of outstanding deficiencies that need to be addressed before substantive review can continue.

Interactive Review

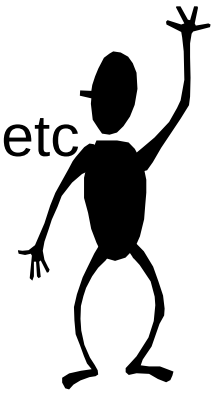
- Informal interaction between FDA and applicants during the review of 510(k) submissions.
- Benefits: Prevent unnecessary delays; Reduce the overall time to market; Ensure that FDA's concerns are clearly communicated; Minimize the number of review cycles; and Ensure timely responses from applicants.
- Interactive review requests do not stop the FDA clock.
- ***NOTE*:** Interactive Review correspondence is not subject to eCopy requirements unless submitted through the Document Control Center.

References:

- Guidance - Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements
- Types of Communication During the Review of Medical Device Submissions - Final Guidance for Industry and Food and Drug Administration Staff

Requests for Additional Information (AI)

- **Why is additional information requested?**
  - Testing data required to demonstrate equivalence.
  - Reviewer has questions regarding labeling, wording, etc.



- **How is additional information requested?**
  - Reviewer request by telephone, email or letter.
  - AI responses are subject to eCopy requirements.

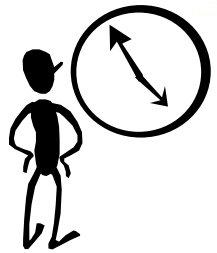
- **How does this affect the submission review times?**
  - Clock stops when submission is officially placed on hold.
  - Up to 180 days to submit response to Document Control Center.

510(k) Submission Process

By Day 90

FDA sends final **MDUFA Decision** on 510(k) (usually by Day 90).

MDUFA III Performance Goals



510(k) Submission Type	FDA Review Days
Traditional and Abbreviated	90
Special	30

Reference:

- MDUFA III Performance Goals

510(k) Submission Process

By Day 100

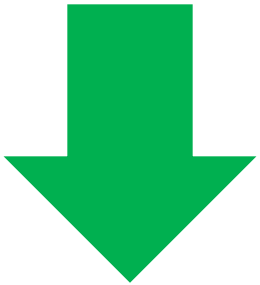
If MDUFA Decision is not reached by Day 100, FDA provides **Missed MDUFA Decision Communication** that identifies outstanding review issues.

Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- **510(k) Decisions**
- Top 510(k) Inquiries from Industry
- References and Resources
- Discussion

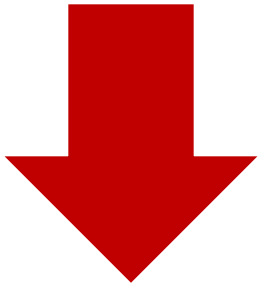
510(k) Decisions

SE Decision



Device To Market.

NSE Decision



Resubmit another 510(k) with new data, PMA, or de novo.

Why might you receive a NSE Decision?

1. There is no predicate device.

2. Your device has a NEW intended use.

3. Your device has different technological characteristics compared to the predicate device and raises new types of questions regarding safety and effectiveness.

4. You did not demonstrate that your device is at least as safe and effective as the predicate.

What Happens After a Device is Cleared?

- The following are posted on the FDA's public online database:
  - SE Letter
  - Indications for Use Form
  - 510(k) Summary (if provided instead of 510(k) Statement)

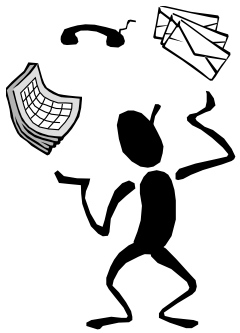
*NOTE: For 510(k) Statements, applicants must make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person.

Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- **Top 510(k) Inquiries from Industry**
- References and Resources
- Discussion

Top 4 - 510(k) Inquiries from Industry

1. Changes to an Existing Device
2. Bundling
3. Transfer 510(k) Ownership
4. Freedom of Information Act (FOIA) Requests



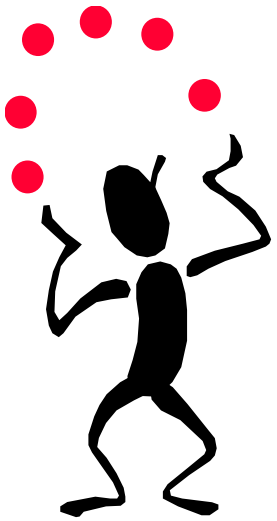
Changes to an Existing Device

- Examples of modifications that may require a 510(k) submission include, but are not limited to, the following:
  - Sterilization method
  - Structural material
  - Manufacturing method
  - Operating parameters or conditions for use
  - Patient or user safety features
  - Sterile barrier packaging material
  - Stability or expiration claims
  - Design

References:

- Is a new 510(k) required for a modification to the device?
- Deciding When to Submit a 510(k) for Change to an Existing Device Guidance

Bundling



- The inclusion of multiple devices or multiple indications for use for a device in a single premarket submission.

- In determining whether a bundled submission can be reviewed during the course of **one review**, FDA may consider whether: (i) the supporting data are similar; (ii) primarily one review division/group will be involved; and (iii) the devices or indications for use are similar.

Reference:

- Guidance Bundling Multiple Devices or Multiple Indications in a Single Submission

Transfer of 510(k) Ownership

- A cleared 510(k) cleared may be bought, sold, or transferred from one owner to another. FDA is not involved in the financial transaction.

- Reminders:
  - New owner should maintain documentation of transfer and all appropriate device records.
  - New owner must manufacturer device according to 510(k) cleared specifications.
  - New and previous owners must update registration and listing.
  - A copy of the transfer should accompany all shipments to the U.S.
  - No new 510(k) clearance letter will be issued.
  - You may inform FDA by submitting Add to File, citing 510(k) number, but this is not required.

Freedom of Information Act (FOIA) Requests

- 510(k) information is subject to public disclosure unless determined by the FDA to be confidential.
- Confidential information is defined under 21 CFR 20.61.
- FOIA Requests can be submitted to the FDA via mail or electronically.

References:

- Freedom of Information Homepage
- How to Make a FOIA Request
- FOI Electronic Requests
- CDRH FOI Reference Sheet

Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Top 510(k) Inquiries from Industry
- **References and Resources**
- **Discussion**

Additional 510(k) References

- Device Advice: Comprehensive Regulatory Assistance: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- How to Market Your Device: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm
- Premarket Submissions: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/default.htm
- Premarket Notification (510k): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
- Content of a 510(k) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm)
- Guidance Format for Traditional and Abbreviated 510(k)s (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)
- Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm
- 510(k) Screening Checklist: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm071360.htm

Additional 510(k) References

- 510(k) Forms : http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070202.htm
- 510(k) Format Tips: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142648.htm
- Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm
- Draft Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm282958.htm
- Premarket Notification [510(k)] Review Fees: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm
- Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345277.htm
- 510(k) Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Regulation & Policy References

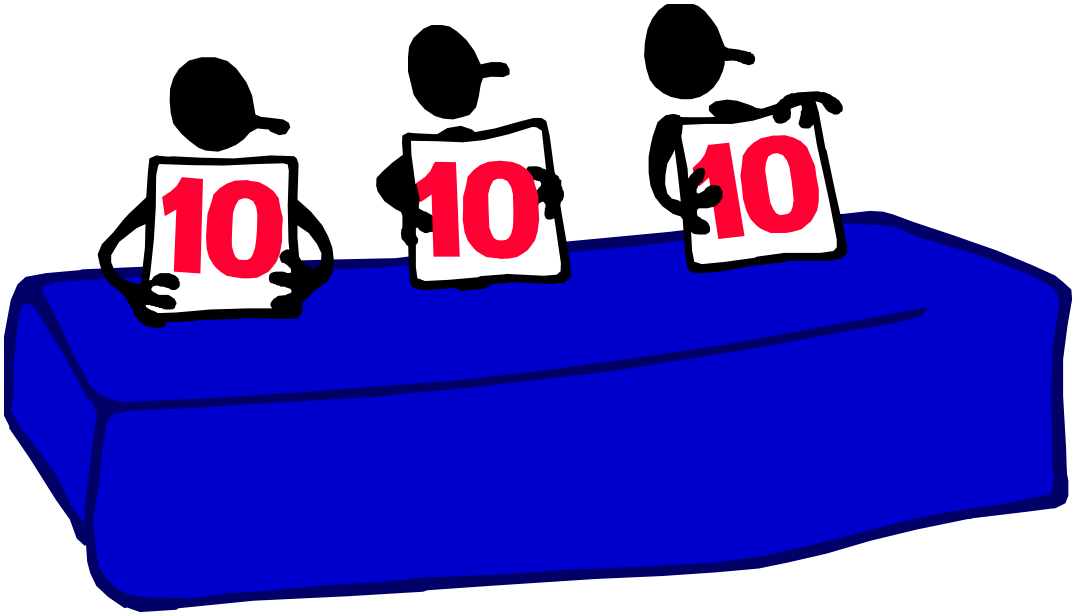
- Food and Drug Administration Safety and Innovation Act (FDASIA): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm
- Medical Device User Fee Amendments 2012 (MDUFA III): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm
- Fact Sheet: Medical Device User Fee Amendments of 2012: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm313695.htm
- CDRH Plan of Action for 510(k) and Science Reports: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm239448.htm
- Plan of Action for Implementation of 510(k) and Science Recommendations: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM239450.pdf
- Medical Device User Fee Rates for Fiscal Year 2014: http://www.gpo.gov/fdsys/pkg/FR-2013-08-02/pdf/2013-18623.pdf

Additional Industry Resources

- **CDRH Learn**
  - Modules include various premarket and post-market information
  - Available 24/7
  - Certificate generated per topic upon passing post-tests, if available
  - http://www.fda.gov/cdrh/cdrhlearn/

- **Division of Industry and Consumer Education (DICE)**
  - 1-800-638-2041
  - DICE@fda.hhs.gov

Your Future 510(k) Submission



Discussion