AdvaMed 510(k) “101” Course

Assembling the 510(k)
Objectives

Upon completion of this module, you will be able to:

- Explain how to select a predicate device, collect information, and format for efficient review
- Describe each section and the content
- Prepare a 510(k)
Agenda

- Predicate devices
  - Intended use
  - Technological characteristics

- Coordinating a submission
  - Medical Device User Fees
  - Submission format
  - Submission contents
Agenda

- 510(k) Paradigm
  - Special 510(k)
  - Abbreviated 510(k)
- Confidentiality and disclosure
- 510(k) clearance and misbranding
When is a 510(k) Submission Required?

- Device is introduced to the market for the first time
- Change in intended use for a marketed device
- Significant modification to a marketed device - changes that significantly enhance or decrease safety or effectiveness
Predicate Devices

Review: What is a predicate device?

- A device on the market before the enactment date of the MDA
- A legally marketed device that has been found by FDA to be substantially equivalent
- A reclassified device
- A de novo device
Predicate Devices

What if there is no predicate?

- Reclassification petition, -or-
- Request for evaluation of an automatic class III designation after receiving an NSE decision because no predicate exists (de novo classification for lower risk devices for which no predicate exists)
Selection of Predicate Devices

- Once you’ve identified the need for a predicate device (or two), how do you find one?
  - FDA databases
  - Product-specific FDA guidance for same/similar products
  - Advertising and labeling for similar devices
  - Published literature
  - Company’s own (earlier generation) device
Selection of Predicate Devices

- How to select an appropriate predicate
  - Find a class I, II or III (not PMA) device/devices with the “same intended use”
  - Find a class I, II or III (not PMA) device/devices with the same or similar technological characteristics or new technological characteristics that do not raise new types of questions of safety or effectiveness
Selection of Predicate Devices

- Products Classification Search
  - Identify product code(s)
  - Look at the specific product codes
  - Check classification regulation(s)

- Releasable 510(k) Search
Selection of Predicate Devices

- Releasable 510(k) Search
  - Search by product code (also can search by 510(k) number, device name, and applicant name)
  - Look at 510(k) information on the specific devices
  - Review submitter’s 510(k) Summaries, FDA Decision Summaries, or obtain Statements
Intended Use

- The intended use of the device is the objective intent of the person legally responsible for labeling of a device.
- Indications for use of a device identify the patient population(s) for which a device can be used, or general or specific conditions a device is intended to treat or diagnose.
Intended Use

• What is the “same intended use”?
  ➔ An identical intended use
  ➔ Same use in a closely related population that poses no additional risks or that is not distinguishable from the predicate’s intended use
Intended Use

- What is the “same intended use”?  
  ➔ One specific indication for use out of a series of indications for use  
  ➔ Same “intended use” but additional specific indications that do not impact safety or effectiveness
Intended Use

- What is a different intended use that may not be substantially equivalent?
  - Use in a closely related but distinguishable population that raises additional significant risks
  - Certain specific indications within a general use that involve new risks
Intended Use

- FDAMA requires FDA to make its substantial equivalence determination on the basis of intended use described in the 510(k) labeling unless certain specified conditions are present.

Technological Characteristics

- In order to be substantially equivalent, two or more devices must have:
  - same technological characteristics;
  - different technological characteristics that could not affect safety or effectiveness; or
  - different technological characteristics that could affect safety or effectiveness but do not raise new types of safety or effectiveness questions AND....
Technological Characteristics

- There are accepted scientific methods for determining whether safety or effectiveness are adversely affected by the differences, and

- There are data to demonstrate that the new technology is at least as safe and effective

- **SE Decision Tree**
Technological Characteristics

- K86-3 (Mohan Memorandum) identified those technological characteristics that should be compared to include:
  - Materials
  - Design
  - Energy Source
  - Performance
Technological Characteristics

- Examples of technological characteristics of devices that were found substantially equivalent:
  - Analog and digital signals (ECG)
  - Different hemodialyzer filter materials
  - Stainless steel and titanium orthopedic implants
  - Capillary zone and gel electrophoresis
Technological Characteristics

- Examples of technological characteristics that were found NOT substantially equivalent:
  - Electrohydraulic v. extracorporeal shock wave lithotripters
  - Hips without coating versus porous coated hips
Next Steps

- You’ve identified a predicate device (or two) with the same indications for use and equivalent technological characteristics and/or performance. 510(k) is the probable route to market.

- Information/data comparing your new device to the predicate has been assembled.
Coordinating 510(k) Preparation

- Establish a 510(k) working group
- Who should be involved?
  - Regulatory Affairs
  - R & D
  - Technical writers
  - Clinical Affairs/Medical Affairs
  - Quality Management
  - Marketing/Commercial Operations
  - Manufacturing Operations
Submission Schedule

- All working group members should understand their roles and deliverables (use templates, forms, examples)
- 510(k) project schedule (including both preparation & review times) should be established in the product development planning phase; include tolerances to allow for product development changes
Submission Schedule

- Allow sufficient time to compile, review, edit, QC, and finalize the 510(k). Pay now or pay later!
- Projections for clearance time can be based on publicly available information for similar devices, or FDA annual report
  - For new/novel devices via 510(k), allow more time.
- Update the schedule regularly
- Communicate changes!
General Content Information

- 21 CFR 807.87, Information Required in a Premarket Notification Submission
- FDA’s Device Advice on 510 (k)s at http://www.fda.gov/cdrh/devadvice/314.html
- FDA guidance, *Format for Traditional and Abbreviated 510(k)s*, August 2005
FDA 510(k) Format Guidance

- Guidance intent is to facilitate timely reviews
- Does not replace device-specific guidances
- 510(k) content divided into 21 sections
- Non-applicable sections should be noted by the company
510(k) Sections

This module will describe the content of each section in order of the Table of Contents

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other
510(k) Format

- Establish a standardized 510(k) format for your company’s use
  - Makes your submissions recognizable (and standardized within your company/division)
  - Accelerates your preparation process
  - Aids in preparing your 510(k) work plan
  - Reduces likelihood of omissions
  - Screening checklist are an aid to ensure you’ve included required elements

- Know your reviewing division’s preferences and build them into your format
Section 1

Medical Device User Fee Cover Sheet

- Medical Device **User Fee Cover Sheet**
- Authorized by MDUFMA of 2002
- Applies to most 510(k)s
- Payment must be received on or before 510(k) is submitted
- Detailed information at:
Device User Fee

- No fee for third-party 510(k)
- No fee for any application intended solely for pediatric use
- Small businesses may qualify for a reduced fee
- Firms with annual gross sales and revenues of $100 million or less, including all affiliates, partners, and parent firms, may qualify
Device User Fee Payment Process

- Register on-line
  - Click on “Create a Medical Device User Fee Cover Sheet” link
  - Click on “New User, Please Register” link to begin registration process. NOTE: If you have registered in the MDUFMA User Fee cover sheet system prior to March 1, 2005, you will need to follow these instructions and consider yourself a new user.
Device User Fee Payment Process

- After your have registered and have received a confirmation via email, you can complete a User Fee Cover Sheet on-line.
- When done, click the SUBMIT button. A form will appear with an electronically generated User Fee Payment Identification Number in the upper right-hand corner. Print at least three copies.

User Fee Cover Sheet (Sample)
Device User Fee Payment Process

- Send a printed copy of the completed User Fee Cover Sheet with your payment
- Be sure to include the Payment Identification Number and the FDA Post Office Box number on your check, bank draft or U.S. Postal money order
Device User Fee Payment Process

If sending by U.S. Mail, send to:
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733
Device User Fee Payment Process

- If using a courier, send payment to:
  U.S. Bank
  Attn: Government Lockbox 956733
  1005 Convention Plaza
  St. Louis, MO 63101
  Ph: 314-418-4821

- For wire transfers, refer to instructions on FDA’s website
Device User Fee Payment Process

- Remember …
  - Include the User Fee Payment Identification Number and FDA PO box number on the check
  - DO NOT send the payment with the 510(k)!
  - DO included a copy of the completed Cover Sheet as the first page of your 510(k)
Section 2

CDRH Premarket Review Cover Sheet

- CDRH Premarket Review Submission Cover Sheet
- The Submission Cover Sheet is a voluntary form
- Provides basic administrative information for all types of premarket notification submissions
- The cover sheet may be obtained at www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf
Section 3
Cover Letter

- Helpful to FDA in the initial processing and review of the 510(k)
- Describes key information (more descriptive) than the CDRH Submission Cover Sheet
- Suggested Cover Letter format is found in Appendix A of the guidance document
Cover Letter

- Submit on your company letterhead
- Identify the type of submission (traditional, special, abbreviated, supplemental information, etc.)
- Device type (in common terms)
- The company submitting the 510(k)
- Contact person(s) (name, title, phone, e:mail)
Cover Letter

- Request for continued confidentiality (under 807.95)
- Your recommended classification regulation
- Classification of your device
- Panel and product code
- File numbers associated with this submission (pre-IDE or 510(k) number)
The basis for your submission:

- new device
- modification of a legally marketed device that would not otherwise qualify for a Special 510(k)
- new indication for use
- new device design
- a submission for a reprocessed, single use, disposable device
- an exempt device which exceeds the limitations for exemption.
Cover Letter

- Note if your device is a convenient kit and the components
- If you are bundling more than one device in your submission, identify all the devices you are bundling and discuss why you believe bundling is appropriate
Cover Letter

Briefly address whether the device:

- Is intended for prescription use
- Is intended for over the counter use
- Contains a tissue/biologic/drug
- Is intended for single use
- Is to be reprocessed
- Uses software
- Is implanted
- Includes clinical data
Section 4
Indications for Use Statement

- **Indications for Use**
  - This section provides the indications for use statement
  - Clearly identify and describe the specific indications for use statement for the device(s) included in the 510(k)
  - Ensure that this is the same (identical) statement used throughout the 510(k) and device labeling
  - Indications for Use Statement Format is located at [www.fda.gov/cdrh/devadvice/314312.html#link](http://www.fda.gov/cdrh/devadvice/314312.html#link)
  - Identify whether the device is intended for prescription use and/or over-the-counter use.
Section 5

510(k) Summary or Statement

- 510(k) Summary or 510(k) Statement
  - 510(k) Summary is a brief summary of the device and of information supporting substantial equivalence
  - 510(k) Statement is a certification that the 510(k) holder will provide a copy of the 510(k), with certain exclusions, within 30 days of a written request
  - Specific verbiage can be located at: obtained at www.fda.gov/cdrh/devadvice/314312.html#link_7
Section 6

Truthful and Accuracy Statement

- **Truthful and Accuracy Statement**
  - 510(k)s must include a statement certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted.
  
  - This form may be obtained at [www.fda.gov/cdrh/manual/stmnt1.html](http://www.fda.gov/cdrh/manual/stmnt1.html).
  
  - The submitter should sign and date the statement.

  - The 510(k) holder (not a consultant) should sign the Truthful and Accuracy Statement.
Section 7

Class III Summary and Certification

- Class III Summary and Certification
  - Required for class III devices for which FDA has not called for PMAs
  - The Class III Summary and Certification provides a review of the risks and adverse events known and associated with the general category of device
  - The Class III Summary and Certification format is located at www.fda.gov/cdrh/manual/stmnciii.html
Section 8
Investigator Financial Disclosure

- Investigator Financial Disclosure/Certification

  ➔ Required if your 510(k) contains information from clinical studies

  ➔ A financial certification and/or a disclosure statement is required for each clinical investigator who participated in your study
Section 8
Investigator Financial Disclosure

- Investigator Financial Disclosure/Certification

The following forms are available on FDA’s website:

- See also 21 CFR Part 54 and the guidance entitled, Financial Disclosure by Clinical Investigators at www.fda.gov/oc/guidance/financialdis.html
Section 9
Declarations of Conformity

- Declarations of Conformity

  ➔ Use this section to provide declarations of conformity to any standards or a summary reports to relevant device-specific guidance(s)

  ➔ We’ll look at an example when we discuss Abbreviated 510(k) later in this module
Declarations of Conformity

If you choose to rely on a recognized standard or a guidance for any part of the device design or testing, include either a

- a declaration of conformity to the standard or summary report
- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed may be used for a traditional 510(k)
- you cannot submit a declaration of conformity for an Abbreviated 510(k) until you have completed the testing
- Additional information regarding the use of declarations of conformity may be obtained at www.fda.gov/cdrh/devadvice/3145.html#link_9
Section 10
Executive Summary

- Executive Summary
  - concise description of the device, including the indications for use and technology; in enough detail to convey an overall understanding of the device
  - device comparison table; outlines
    - Similarities & differences with the predicate
    - How these support a substantial equivalence decision
Executive Summary

Provide summary of performance testing, including:
- Type of testing
- Methods used
- Conclusions of the results
- Focus of summaries from Sections 18 (Bench), 19 (Animal), 20 (Clinical)
Section 11
Device Description

- Describe the device; include:
  - Design Requirements
  - Performance specifications
  - All models, accessories, and key components included in the submission
  - Physical description - size, appearance, materials (include all patient contacting components and materials)
  - Functional description-how does it work?
  - Photographs, drawings, schematics if helpful
Section 12
Substantial Equivalence

- Provide detailed information about the predicate device(s) including:
  - Trade Name/Model Number
  - 510(k) holder/submitter
  - 510(k) Docket Number (if known)

- A detailed comparison of your device and the predicates device(s) sufficient to establish substantial equivalence, as appropriate, in terms of:
  - Indications for use
  - Technological characteristics
  - Performance specifications
Substantial Equivalence

- Rationale to support SE
  - FDA Decision Tree can be included in 510(k) for ease of review. The flowchart is located at: www.fda.gov/cdrh/ode/dd510kse.pdf
  - Device comparisons can be presented in *tabular form*, narrative form, or both
  - Refer to supporting evidence in appendices
  - State conclusion(s) regarding substantial equivalence of your device and the predicate device(s)
Section 13
Proposed Labeling

- The 510(k) must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e).
- IVD devices should additionally satisfy the requirements of 21 CFR 809.10.
- “Labeling” includes the device label, instructions for use, and any patient labeling.
- Labeling Requirements are found at www.fda.gov/cdrh/devadvice/314312.html#link_10
- Refer to device specific guidance for additional labeling requirements.
Section 14
Sterilization and Shelf Life

- For devices sold as sterile, follow the guidance, Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA, at www.fda.gov/cdrh/ode/guidance/361.html

- For devices that are reprocessed single use devices, refer to Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices at www.fda.gov/cdrh/ode/guidance/1216.html

- For a submission that identifies a shelf life for the device, shelf life claims should be supported by appropriate bench tests and/or sterilization (packaging) validation
Section 15
Biocompatibility

- For devices containing components that come into direct or indirect contact with patients, evaluate the biocompatibility of the patient-contacting materials.

- Refer to Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing at [www.fda.gov/cdrh/g951.html](http://www.fda.gov/cdrh/g951.html)

- Submit data and summaries from designated biocompatibility tests appropriate to your device design including pass/fail criteria.
Biocompatibility

- If identical materials are used in a predicate with the same type and duration of patient contact, you may identify the predicate in lieu of performing biocompatibility testing and state that your device is comprised of identical materials and that are processed by identical manufacturing methods.

- This is most appropriate when you are the manufacturer of the predicate and you have complete documentation with respect to the manufacturing methods and materials employed.
Section 16
Software

- This section should include the appropriate software documentation as described in the guidance titled Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices at www.fda.gov/cdrh/ode/guidance/337.html
- Identify the “level of concern,” (minor, moderate, or major) associated with your device and provide documentation consistent with that level
Section 17

Electromagnetic Compatibility

- Devices that include an electronic component should evaluate electromagnetic compatibility including emissions and immunity

- Provide test summary data according to IEC 60601-1-2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) or equivalent method

- For devices designed to have patient contact with any electrically powered component, FDA recommends that you follow IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995) or an equivalent method
Section 18
Bench Testing

- Describe the bench testing and provide the results that support the performance characteristics

- Submissions should include the information below;
  - the specific bench tests conducted
  - describe each test protocol
  - summarize the results
  - describe your analysis
  - discuss your conclusions

- Utilize relevant device-specific guidance as available
Bench Testing

- Descriptions of test protocols should identify the:
  - objective of the test
  - test articles used in the test
  - test methods and procedures (including any specific test conditions)
  - study endpoint, i.e., the specific parameter measured
  - pre-defined acceptance or pass/fail criteria.
Bench Testing

- In the summary of your results and analysis, briefly present the data derived from testing in a clear and concise form, such as a table or graphs.

- The conclusions should describe any comparison testing with the predicate in terms of substantial equivalence.

- IVD bench testing should refer to assay-specific guidance documents.
Section 18
Animal Testing

- Describe the animal testing and provide the results that support the performance characteristics
- Submissions should include the information below;
  - the specific animal tests conducted
  - describe each test protocol
  - summarize the results
  - describe your analysis
  - discuss your conclusions
- Utilize relevant device-specific guidance as available
Animal Testing

- Descriptions of test protocols should identify the:
  - objective of the test
  - test articles used in the test
  - test methods and procedures (including any specific test conditions)
  - study endpoint, i.e., the specific parameter measured
  - pre-defined acceptance or pass/fail criteria.
Animal Testing

- In the summary of your results and analysis, briefly present the data derived from testing in a clear and concise form, such as a table or graphs.

- The conclusions should describe any comparison testing with the predicate in terms of substantial equivalence.

- IVD bench testing should refer to assay-specific guidance documents.
Section 20
Clinical Testing

- The need for clinical testing depends on many factors including device type, intended use, design, safety profile, and clinical experience.
- Consult your reviewing Branch or device-specific guidance for clinical trial requirements for your device.
- Provide the clinical protocol that identifies the:
  - objective of the test
  - test methods and procedures (including any specific test conditions)
  - study endpoints (usually both safety and effectiveness)
  - statistical methodology used
Clinical Testing

- Discuss the study results, analyses performed (including statistical, as appropriate), and conclusions
- Discuss any comparison testing with the predicate device in terms of substantial equivalence
- Significant risk studies must be conducted under the IDE regulation, 21 CFR Part 812 (if conducted in the US)
- Non-significant risk studies are subject to the abbreviated requirements of 21 CFR Part 812.2(b)
- Sponsors of clinical trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50)
Clinical Testing

- In the summary of your results and analysis, present the data derived from testing in a clear and concise form, such as tables or graphs.

- The conclusions should describe any comparison testing with the predicate in terms of substantial equivalence.

- IVD bench testing should refer to assay-specific guidance documents.

- Line listing data may be required (consult your Branch for details).
Clinical Testing

- Other Notes:
  - FDA does accept foreign data; follow appropriate regulations regarding ethics boards, patient protection and study conduct
  - Ensure data integrity through monitoring and auditing of studies
  - Obtain statistical assistance as appropriate to determine number of patients required and data analysis methods
Test Your Learning
QUESTION 1

- Identify correct statements about predicate devices:
  
a) A device legally marketed prior to May 28, 1976

b) A class 1, II or III (not PMA) device with the same intended use, raising new issues with safety or efficacy

c) A device re-classified from class III to II or I
QUESTION 2

- Who does not need to submit a 510(k)
  1) A manufacturer whose device is the same as a competitors
  2) A re-packager who does not alter labeling
  3) A relabeler who changes an intended use
QUESTION 3

- What are some of the roles a regulatory professional may play in the 510(k) process?
QUESTION 4

- Describe the content expected for biocompatibility, bench testing, and/or clinical data?
QUESTION 5

The following is ALWAYS required in a 510(k):

1) Class III certification
2) Manufacturing information
3) A summary of safety and effectiveness information
4) Substantial equivalence information
QUESTION 6

How must the technological characteristics of a new device and its predicate be related?

1) They must be the same
2) They must raise no new questions of safety or effectiveness
3) There must be methods to compare them
QUESTION 7

- Who must sign the truthful and accurate statement?

1) Responsible person required to submit the 510(k)
2) The R & D designate
3) The most responsible management of the company
4) The person who can best vouch for the information in the submission
QUESTION 8

- A device description should include:
  1) A description of the physical properties of a device
  2) Information showing a comparison between the predicate and new device
  3) A description of how the device works
QUESTION 9

- What are some sources that you can check to identify a predicate device for your company’s new product?
QUESTION 10

- Why include data if the similarity and differences comparison shows substantial equivalence? When may *clinical* data be required in a 510(k) submission? What types of *nonclinical* data may be needed?
Handy Tips

- Include all required elements
- Be sure you have reviewed and, where appropriate, incorporated all applicable information
  - 21 CFR 807.87
  - 510(k) Screening Checklist and Cover Sheet
  - General and device specific guidances
  - Previous 510(k)s and questions
Handy Tips

- Write clearly and concisely
- Do not be afraid to repeat key points, state conclusions, be persuasive
- Organize well; the submission must flow well and be easy to follow
- Begin each section on a new page and separate each section with tabs
Handy Tips

- Be internally consistent (both text and data)
- Provide titles and/or numbers for diagrams, figures, and tables. Make sure citations in text match
- Explain all deviations or omissions
Handy Tips

- Where device characteristics are identical, say so **explicitly**
- Use an objective reviewer for final submission; remember the FDA reviewer may never see the device
Handy Tips

- Make sure copies are clear
- Left margin 1.5”; 8.5” x 11” paper; 3 hole punch
- Put in an inexpensive binder
- Include a Table of Contents
- Number all pages
- Cross reference properly
Formats

- ODE is encouraging 510(k) submitters to include an electronic copy with the paper copies
  - An electronic copy is an exact duplicate of a paper submission on a CD or DVD
  - Web link: http://www.fda.gov/cdrh/elecsub.html

- OIVD is utilizing the Turbo-510(k) program for electronic submissions
  - Information can be found on OIVD’s website
Formats

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STED Format

- FDA is participating in a pilot program to evaluate harmonized alternatives for premarket procedures
- The draft STED document is outlined in the FDA guidance document “A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures”
- The 510(k) format document contains a comparison table for use when a STED 510(k) submission
QUESTIONS?

- How to resolve questions about the type, extent, presentation of information/data in a 510(k)?
  - Prior 510(k)s
  - Colleagues in trade and professional organizations
  - Consultants
  - FDA
The 510(k) Paradigm

- CDRH Re-engineering provided for two new types of 510(k) submissions that cover specific situations
  - Special 510(k)
  - Abbreviated 510(k)
- **510(k) Paradigm Flowchart**
Special 510(k)

- For **modified** devices
  - Manufacturer modifies its own legally marketed device and determines that a 510(k) is required
  - Modification does not affect intended use or fundamental scientific technology
Special 510(k)

- Manufacturer assesses modification in accordance with 21 CFR 820.30, Design Controls
- 510(k) submitted with “Declaration of Conformity” to design controls
- FDA processes the 510(k) in less than 30 days
Special 510(k)

- Format for Special 510(k)
  - Medical Device User Fee Cover Sheet
  - CDRH Premarket Review Submission Cover Sheet
  - Cover Letter
  - Indications for Use
  - 510(k) Summary or 510(k) Statement
  - Truthful and Accuracy Statement
Special 510(k)

- Format for Special 510(k) (continued)
  - Name of the legally marketed device that is being modified and the 510(k) number under which it was cleared
  - Classification, Panel, and Product Code
  - Description of Modified Device and Comparison to Cleared Device
  - Proposed Labeling
Special 510(k)

Format for Special 510(k) (continued)

⇒ Summary of Design Control Activities
  • Risk analysis method(s) used to assess impact of the modification on the device
  • Results of risk analysis
  • Verification and/or validation activities required (including methods and acceptance criteria)
Special 510(k)

Format for Special 510(k) (continued)

- Declaration of Conformity with Design Controls
  - Statement that all V/V activities were performed and results demonstrate that the acceptance criteria were met
  - Statement that manufacturing facility is in conformance with design control procedure requirements
  - Signature of designated individual
Abbreviated 510(k)

- Manufacturer intends to market new reserved class I, class II or preamendment class III device
- Device is subject to special controls, FDA guidance, and/or recognized standard/s, which manufacturer has followed
Abbreviated 510(k)

- Format for an Abbreviated 510(k)
  ➔ Includes all required elements of 21 CFR 807.87
  ➔ Refer to FDA guidance, Format for Traditional and Abbreviated 510(k)s, August 2005
Abbreviated 510(k)

- Format for an Abbreviated 510(k) (continued)

  ➔ For a submission that relies on a guidance document and/or special controls, include the summary report describing how these were used to address the risks associated with the particular kind of device.
Abbreviated 510(k)

Format for an Abbreviated 510(k) (continued)

- For a submission that relies on a recognized standard, a Declaration of Conformity to a Recognized Standard

- Include data summaries and/or information to address areas not covered by standards or special controls
Confidentiality and Disclosure

- Existence of 510(k) and its contents are confidential until found SE, unless disclosed by submitter
- Submission should be marked confidential as appropriate
- A separate, redacted copy may be submitted when/if a copy of your 510(k) is requested through FOI
-Submitter has opportunity to review before FDA release under FOI
510(k) “Approval”

- 21 CFR 807.97 covers misbranding by reference to premarket notification.
- For a 510(k) product, you cannot create an impression of official approval of the device.
- FDA has determined that a company can announce clearance of device, via a press release or in advertising, in the immediate period following receipt of clearance letter.