

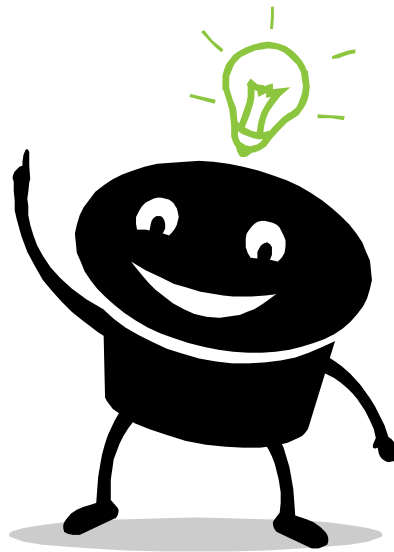
# **The 510(k) Program**

**FDA Small Business  
Regulatory Education for Industry (REdI)  
Silver Spring, MD  
September 27, 2016**

**CDR Kimberly Piermatteo, MHA**

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 the most prolific way to bring a new  
device to market.**



# Poll Question

DEV-D1S5-1

View Votes
Edit
End Poll

What is your 510(k) experience?

<input type="radio"/> Never submitted a 510(k)		0%	(0)
<input type="radio"/> Have submitted a 510(k)		0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

# Learning Objectives

1. Review what a 510(k) is and when it is required
2. Learn how to prepare a 510(k)
3. Discuss how FDA reviews a 510(k)
4. Learn what a 510(k) decision means
5. Discuss common questions about 510(k)s

# Presentation Outline

- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Common 510(k) Questions
- Summary

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# Classes of Medical Devices

Class	Risk	Controls	Submission Type
I	Lowest	General	<ul style="list-style-type: none"><li>• Exempt</li><li>• 510(k)</li></ul>
II	Moderate	General and Special (if available)	<ul style="list-style-type: none"><li>• Exempt</li><li>• 510(k)</li></ul>
III	Highest	General and PMA	<ul style="list-style-type: none"><li>• PMA</li><li>• HDE</li></ul>

## References:

- [Regulatory Controls](#)
- [Class I/II Exemptions](#)

- A 510(k) is:**
- Section 510(k) of Federal FD&C Act
  - A Premarket Notification
  - 21 CFR 807 Subpart E
  - A marketing clearance application
  - Allows FDA to determine Substantial Equivalence (SE)
  - Reviewed in 90 Calendar Days (MDUFA review goal)

- A 510(k) is not:**
- A Form
  - Establishment Registration
  - Device Listing
  - Premarket Approval (PMA)

Reference:

- [Premarket Notification \(510k\)](#)



# What is Substantial Equivalence?

- Demonstration that a new device, as compared to a legally marketed device (also known as a predicate device), has...
  - the same intended use **and**
  - the same technological characteristics,
    - **Or** differences in technological characteristics do not raise different questions regarding safety and effectiveness

## References:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)
- [CDRH Learn Module “The 510\(k\) Program Guidance: Evaluating Substantial Equivalence in Premarket Notifications” \[8/15/2014\]](#)

# 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 and Effectively Use Predicate Devices](#)
- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Section IV.C. Predicate Device\(s\)](#)

# Product Codes

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

## References:

- [Guidance - Medical Device Classification Product Codes](#)
- [Product Classification Database](#)

# Example: Product Classification Database

## Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

### Search Database



Help



Download Files

Device

Product Code

Review Panel

Regulation Number

SubmissionType

Third Party Eligible

Implanted Device  Life-Sustain/Support Device

Device Class

[Go to Quick Search](#)

[Clear Form](#)

# Example: Product Classification Database

## Product Classification

◀ FDA Home ▶ Medical Devices ▶ Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

infusion

Search

[Advanced Search](#)

# Example:

## Product Classification Database

Device	Pump, Infusion
Regulation Description	Infusion pump.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FRN
Premarket Review	<a href="#">Office of Device Evaluation (ODE)</a> Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) General Hospital Devices Branch (GHDB)
Submission Type	510(k)
Regulation Number	<a href="#">880.5725</a>
Device Class	2
Total Product Life Cycle (TPLC)	<a href="#">TPLC Product Code Report</a>
GMP Exempt?	No
<b>Recognized Consensus Standards</b>	
<ul style="list-style-type: none"><li>1-79 ISO 26825 First edition 2008-08-15 <a href="#">Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance</a></li><li>6-68 ISO 7886-2 First edition 1996-05-15 <a href="#">Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps</a></li><li>6-273 ISO 23908 First edition 2011-06-11 <a href="#">Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling</a></li><li>6-366 ISO /FDIS 9626 Second edition 2016-XX-XX <a href="#">Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods</a></li></ul>	
<b>Guidance Documents</b>	
<ul style="list-style-type: none"><li>Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions <a href="#">PDF</a></li><li>Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps</li></ul>	
Implanted Device?	No
Life-Sustain/Support Device?	No
<b>Third Party Review</b>	
<ul style="list-style-type: none"><li>Eligible for <a href="#">Accredited Persons Program</a></li></ul>	
<b>Accredited Persons</b>	
<ul style="list-style-type: none"><li><a href="#">Bsi Healthcare</a></li><li><a href="#">Center For Measurement Standards Of Industrial</a></li><li><a href="#">Dekra Certification B.v.</a></li><li><a href="#">Regulatory Technology Services, Llc</a></li><li><a href="#">Third Party Review Group, Llc</a></li><li><a href="#">Tuv Sud America Inc.</a></li></ul>	

# Example: Product Classification Database

Device	Pump, Infusion
Regulation Description	Infusion pump.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FRN
Premarket Review	<u>Office of Device Evaluation (ODE)</u> Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) General Hospital Devices Branch (GHDB)
Submission Type	510(k)
Regulation Number	<u>000.5725</u>
Device Class	2
Total Product Life Cycle (TPLC)	<u>TPLC Product Code Report</u>
GMP Exempt?	No

# When is a 510(k) Typically Required?

- **New Device**
  - Introducing a device to the market for the first time
- **Modification to a Legally Marketed Device**
  - Change in indications for use
  - Significant change(s) in design

## References:

- [Is a new 510\(k\) required for a modification to the device?](#)
- [Guidance - Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](#)



# What do you do if...

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



Consider *de novo*

# **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 may be used under any circumstance**

## References:

- [How to Prepare A Traditional 510\(k\)](#)
- [510\(k\) Forms](#)

# Abbreviated 510(k)

- Required elements (21 CFR 807.87)
- **Use/reference guidance documents, special controls, and recognized standards**
- Under certain conditions, submitters may not need to submit test data

Reference:

- [How to Prepare An Abbreviated 510\(k\)](#)

# Special 510(k)

- Required elements (21 CFR 807.87)
- **Device modification to a submitter's own legally marketed device**
- Modification does NOT affect the intended use or fundamental scientific technology
- Specific data are generally not submitted by sponsor nor evaluated by FDA
- FDA Review - 30 Calendar Days

Reference:

- [How to Prepare A Special 510\(k\)](#)

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# Poll Question

DEV-D1S5-2

View Votes

Edit

End Poll

How knowledgeable are you about the content of a 510(k)?

<input type="radio"/> Very	<div></div>	0%	(0)
<input type="radio"/> Somewhat	<div></div>	0%	(0)
<input type="radio"/> Not very	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

# Content of a 510(k)

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
- 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, Animal or Clinical**
- Other



# Intended Use and Indications for Use

- **Intended Use:** General purpose of the device or its function, and encompasses the indications for use
  - **Indications for Use:** As defined in 21 CFR 814.20(b)(3)(i), describes 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)
- Recommended Format for Indications for Use Statement ([Form FDA 3881](#))

# 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 will verify the accuracy and completeness of the 510(k) Summary information

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Appendix B. The 510\(k\) Summary Document Requirements](#)



# FDA Recognized Consensus Standards (Declarations of Conformity)

- Voluntary program
- Used to simplify and streamline the 510(k) review process
- Submitters 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 - Recognition and Use of Consensus Standards](#)
- [Guidance - Frequently Asked Questions on Recognition of Consensus Standards](#)
- [Recognized Consensus Standards Database](#)
- [CDRH Learn Modules Available](#)

# 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:

- [Guidance Documents \(Medical Devices and Radiation-Emitting Products\)](#)

# Recap Infusion Pump Example

## ([Product Classification Database](#))



### Recognized Consensus Standards

- [ISO 7886-2 First edition 1996-05-15 Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps](#)
- [ISO 26825 First edition 2008-08-15 Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance](#)
- [ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling](#)
- [ISO 9626 First edition 1991-09-01 Stainless steel needle tubing for the manufacture of medical devices \[Including: Amendment 1 \(2001\)\]](#)



### Guidance Documents

- [Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification \[510\(k\)\] Submissions](#) **Text**
- [Guidance on the Content of Premarket Notification \[510\(k\)\] Submissions for External Infusion Pumps](#)

# Device Description

- Overall device design
  - Physical specifications, dimensions, design tolerances, engineering drawings, figures, etc.
- Materials
  - List all patient contacting components
- Energy sources
- Other key technological features

# Substantial Equivalence Discussion

*(Decision Points from 510(k) Decision-Making Flowchart)*

1. Is the predicate device legally marketed?
2. Do the devices have the same intended use?
3. Do the devices have the same technological characteristics?
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?
5. Two Parts:
  - a) Are the methods acceptable?
  - b) Do the data demonstrate substantial equivalence?

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Appendix A. 510\(k\) Decision-Making Flowchart](https://www.fda.gov/oc/ohrt/510k/510k-decision-making-flowchart)

# Substantial Equivalence and Predicate Devices

- 510(k) review standard is comparative
  - **Primary predicate**
  - **Multiple predicates**
  - **Reference device**
    - Supports scientific methodology or standard reference values
    - Is not a predicate device
  - **Split predicates**
    - Inconsistent with 510(k) regulatory standard

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)



# Proposed Labeling

- Comply with Device Labeling Requirements ([21 CFR 801](#) or [809.10](#))
- 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 predicate device labeling is recommended

## Reference:

- [Introduction to Medical Device Labeling](#)

# 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 and standards
- Consider comparative testing to demonstrate substantial equivalence
- Include: test methods, acceptance criteria and test results for review

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Section IV.F. Requests for Performance Data](#)

# 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
- Be consistent throughout the submission
- Follow current applicable guidance documents and device specific checklists

# Questions about Your 510(k) Content?

- Consider the **Pre-Submission Program**
  - Method to obtain feedback from the FDA
  - Typically for unique situations (e.g. need for clinical data)
  - Request either a formal written response, meeting, or teleconference to address your questions

## References:

- [Guidance - Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff \[Pre-Sub for a 510\(k\) is under Appendix 1.C\]](#)
- [CDRH Learn Modules Available](#)

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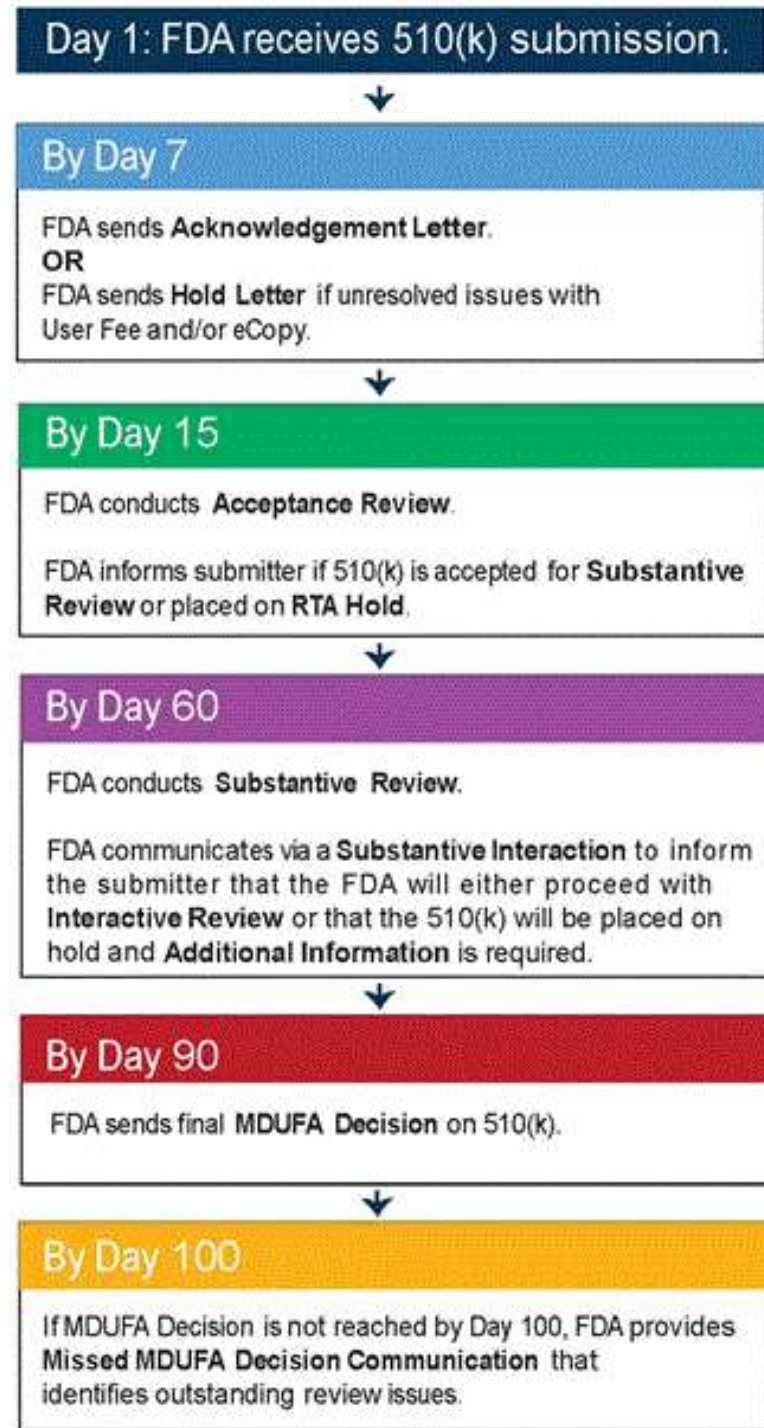
# 510(k) Submission Process

## 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](#)
- [Guidance - Types of Communication During the Review of Medical Device Submissions](#)
- [Guidance – FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)





# Key Aspects of the 510(k) Submission Process

- User Fee and/or eCopy Check
- Refuse to Accept (RTA) Policy
- Substantive Interaction
  - Interactive Review
  - Additional Information (AI) Requests

# User Fee and/or eCopy Check

- By Day 7
- User Fee Paid
  - For FY2017, the Standard User Fee is \$4,690 and the Small Business Fee is \$2,345
- Valid eCopy
  - Must submit **two copies**; one paper copy and one eCopy

## References:

- [Guidance - FY 2017 Medical Device User Fee Small Business Qualification and Certification](#)
- [eCopy Program for Medical Device Submissions](#)



# Refuse to Accept (RTA) Policy

- By Day 15
- [Guidance – Refuse to Accept Policy for 510\(k\)s \(Aug. 4, 2015\)](#)
- Is the 510(k) submission administratively complete for substantive review?
- Necessary elements and content of a complete 510(k) submission
- **FDA clock begins on the date of receipt when the 510(k) is “accepted for review”**

# Substantive Interaction

- By Day 60
- FDA will notify submitter:
  1. The 510(k) will not be placed on hold and outstanding deficiencies will be resolved via **Interactive Review**; or
  2. The 510(k) is being placed on hold via an **Additional Information** request which identifies the outstanding deficiencies that need to be addressed before substantive review can continue



# Interactive Review

- Informal interaction between FDA and submitters
- FDA review clock does not stop
- Not subject to eCopy requirements unless submitted through the Document Control Center (DCC)
- Benefits: Ensures FDA's concerns are clearly communicated and reduces overall time to a decision

# Additional Information (AI) Requests

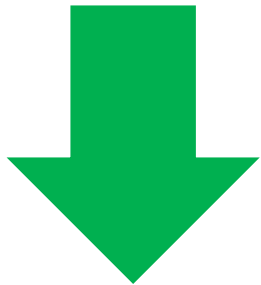
- Additional information is necessary to continue or complete the 510(k) review
- 510(k) submission is placed on hold and FDA review clock stops
- Submitter has up to 180 calendar days from the date of the AI Request to provide a complete response to DCC
- AI Responses are subject to eCopy requirements

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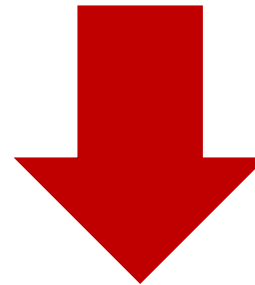
# 510(k) Decisions

## SE Decision



Device To Market

## NSE Decision



Resubmit another 510(k)  
with new data, PMA, *de novo*  
or reclassification petition

# Why Might You Receive a NSE Decision?

1. There is no predicate device
2. Your device has a NEW intended use compared to the predicate device
3. Your device has different technological characteristics compared to the predicate device and raises different questions regarding safety and effectiveness
4. You did not demonstrate that your device is at least as safe and effective as the predicate

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Section IV.A.3. Categories of NSE Determinations](#)

# What Happens After a Device is Cleared?

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

*\*NOTE: For [510\(k\) Statements](#), submitters must make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person (21 CFR 807.93).*



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# Changes to an Existing Device

- A new 510(k) is needed when a change, or the sum of the incremental changes "could significantly affect the safety or effectiveness of the device" ([21 CFR 807.81\(a\)\(3\)](#))
- Changes to the following may require a new 510(k):
  - Intended Use
  - Design
  - Materials
  - Sterilization Method
- If no new 510(k) is needed, document the decision-making process and the basis for the conclusion per compliance with the [Quality System Regulation \(21 CFR 820\)](#)

# UPDATE: Changes to an Existing Device

- On August 5, 2016, FDA released two draft guidance documents:
  - [Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#)
    - Applies to medical device changes broadly
  - [Deciding When to Submit a 510\(k\) for a Software Change to an Existing Device](#)
    - Focuses on software-specific changes
- Draft Guidance include:
  - Clarification of key terms
  - Explanation on how to use risk assessment (*primarily derived from ISO 14971*)
  - Updated flowcharts
  - Specific examples of changes that would or would not require a new 510(k)
- Open for public comment ([FDA-2016-D-2021](#); [FDA-2011-D-0453](#))

# Bundling

- The inclusion of multiple devices or multiple indications for use for a device in a single premarket submission
- When is bundling appropriate?
  - If supporting data are similar
  - If one division can conduct the premarket review
  - If 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) 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 manufacture 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
- No new 510(k) clearance letter will be issued

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# Summary

1. A 510(k) is a complete premarket submission.
2. The 510(k) review standard is comparative.
3. A 510(k) should contain all the content necessary to demonstrate the safety and effectiveness of the new device compared to a predicate device is substantially equivalent.
4. During the review of a 510(k), FDA will communicate with submitters based on specified performance goals.
5. A 510(k) found substantially equivalent is considered “cleared” by the FDA and may then be legally marketed in the U.S.

# Questions

Please complete the session survey:

[surveymonkey.com/r/DEV-D1S5](https://surveymonkey.com/r/DEV-D1S5)



# Call to Action

- Utilize the 510(k) Decision-Making Flowchart
- Identify relevant resources and references (e.g., Guidance Documents, CDRH Learn Modules, contact DICE either by phone or [e-mail](#), etc.)

