U.S. FOOD & DRUG ADMINISTRATION

Three Keys Concepts: An Overview of the 510(k) Program

AMDM OIR Submissions Workshop
April 16, 2018

Sara Aguel, Policy Analyst
OIR/DPOM

510(k)s have been a part of CDRH's mission for over 40 years

1976

President Gerald Ford signs the Medical Device Amendments

2017

One Hundred Fifteenth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and seventeen

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

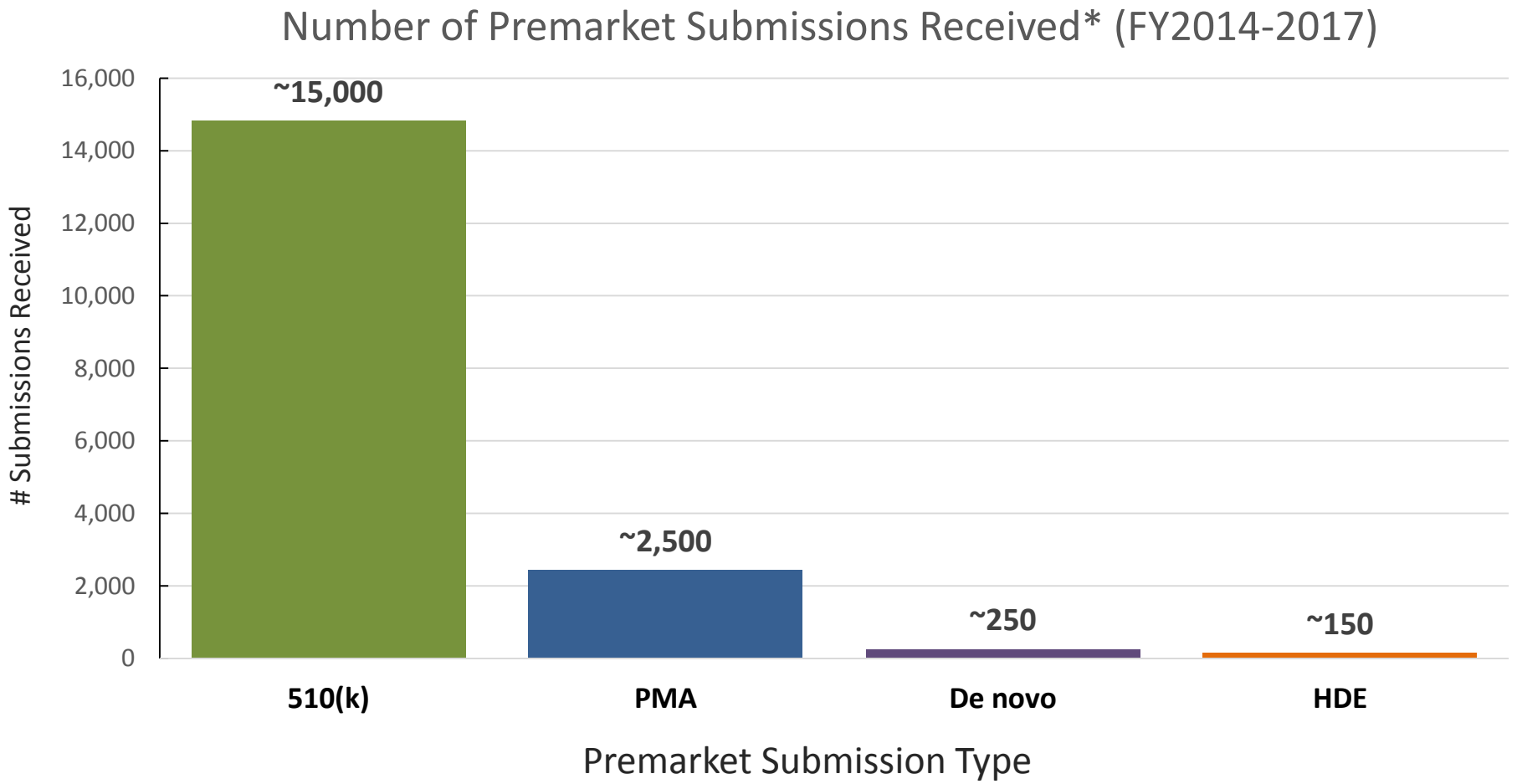
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "FDA Reauthorization Act of 2017".

FDA Reauthorization Act (MDUFA IV)

For devices that require authorization, 510(k) is the primary path to the U.S. market



Source: MDUFA III Quarterly and Annual Reports (510(k), PMA, and De novo) and internal data (HDE)
*510(k) and De novo numbers include all Originals. PMA and HDE numbers include all Originals and some Supplements

There's a lot to know about 510(k)s, and it can be difficult to know where to begin

FDA shares AMDM's commitment to industry education

Understanding 510(k) begins with three key concepts

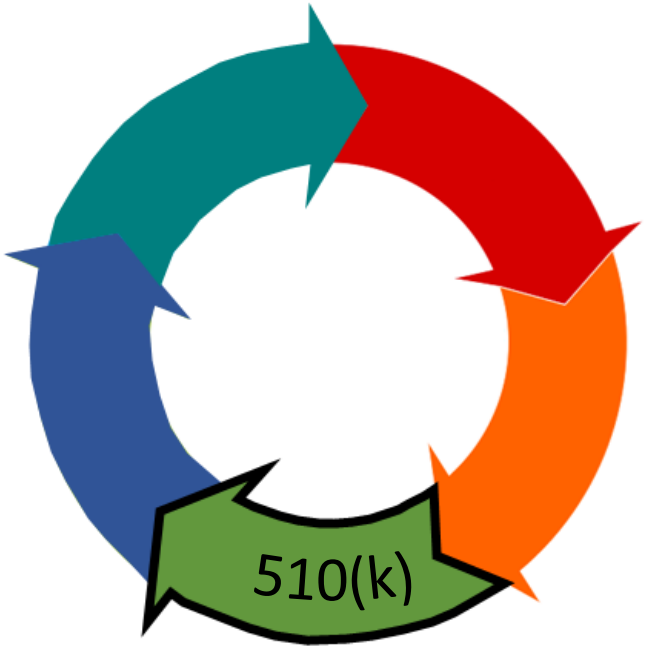
1. Regulatory Context
2. Essential Processes
3. Resources

Understanding 510(k) begins with three key concepts

1. Regulatory Context
2. Essential Processes
3. Resources

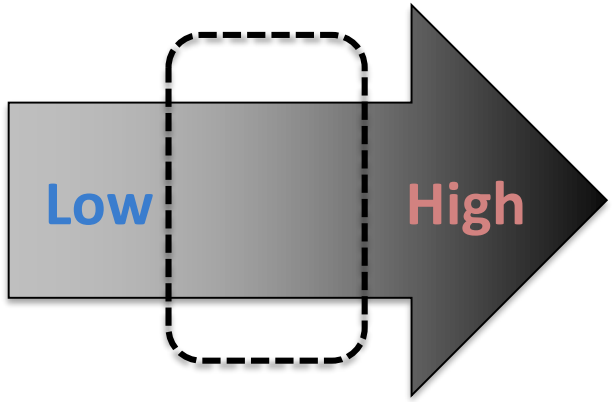
510(k)s are one part of a large regulatory ecosystem

Device Life Cycle



Type of Premarket submission

Risk

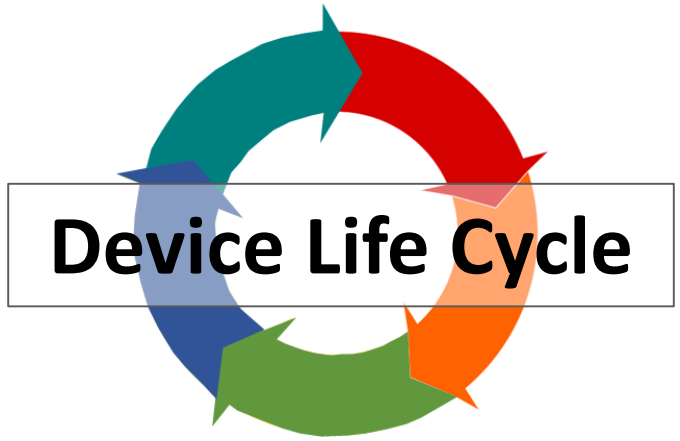


Moderate Risk devices

Review Standard

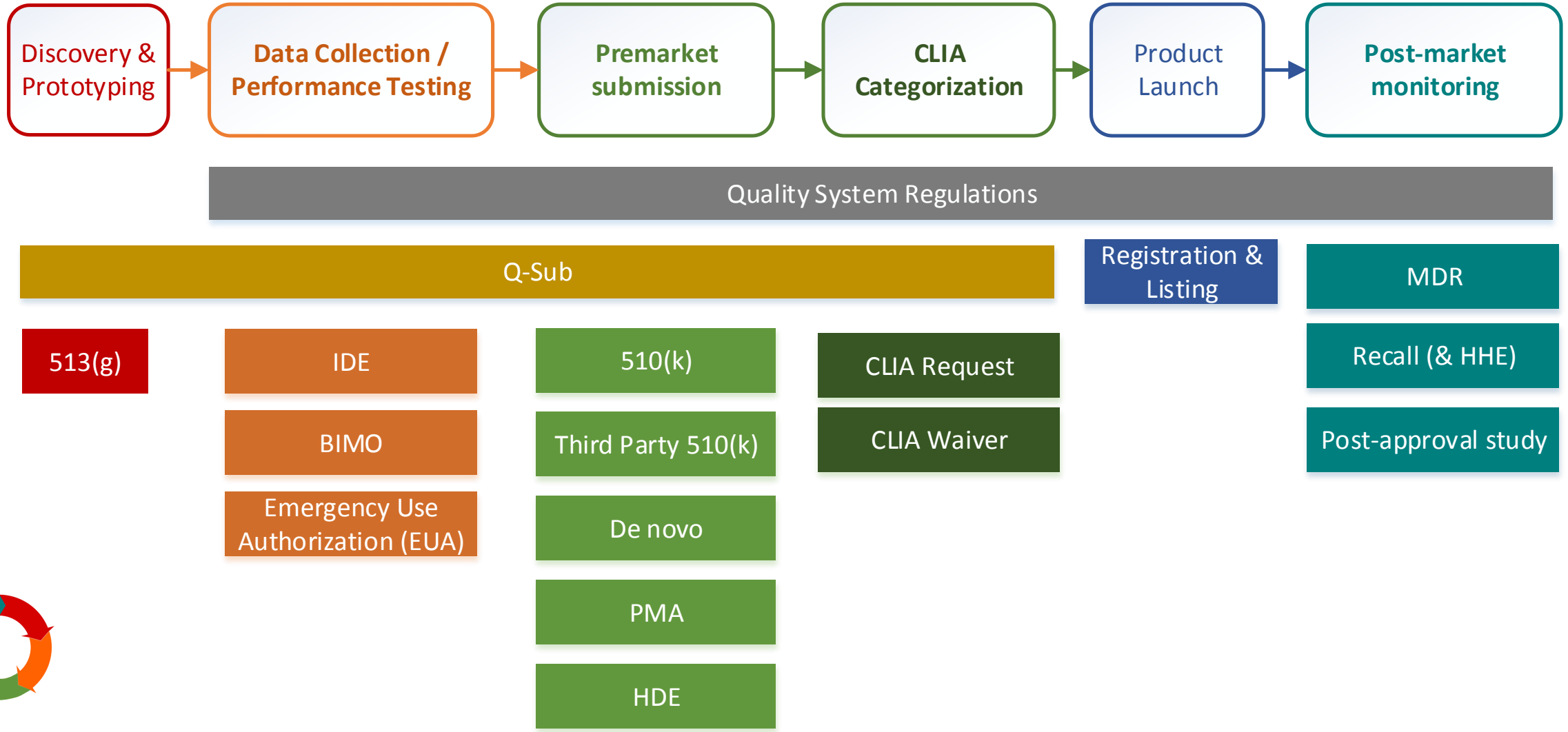
Compared to a predicate

A device goes through several steps throughout its life cycle

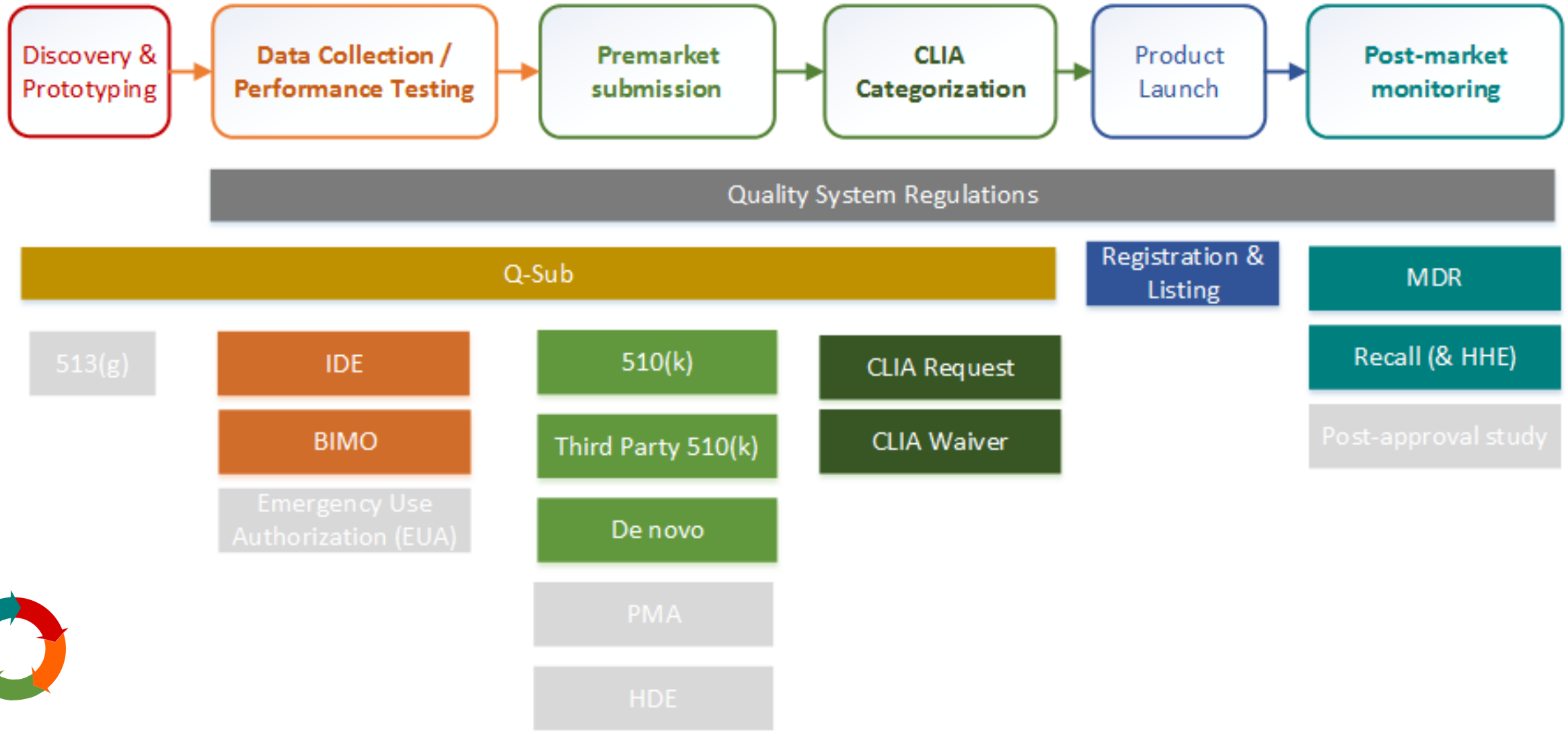


Discovery & Prototyping → Data Collection / Performance Testing → Premarket submission → CLIA Categorization → Product Launch → Post-market monitoring

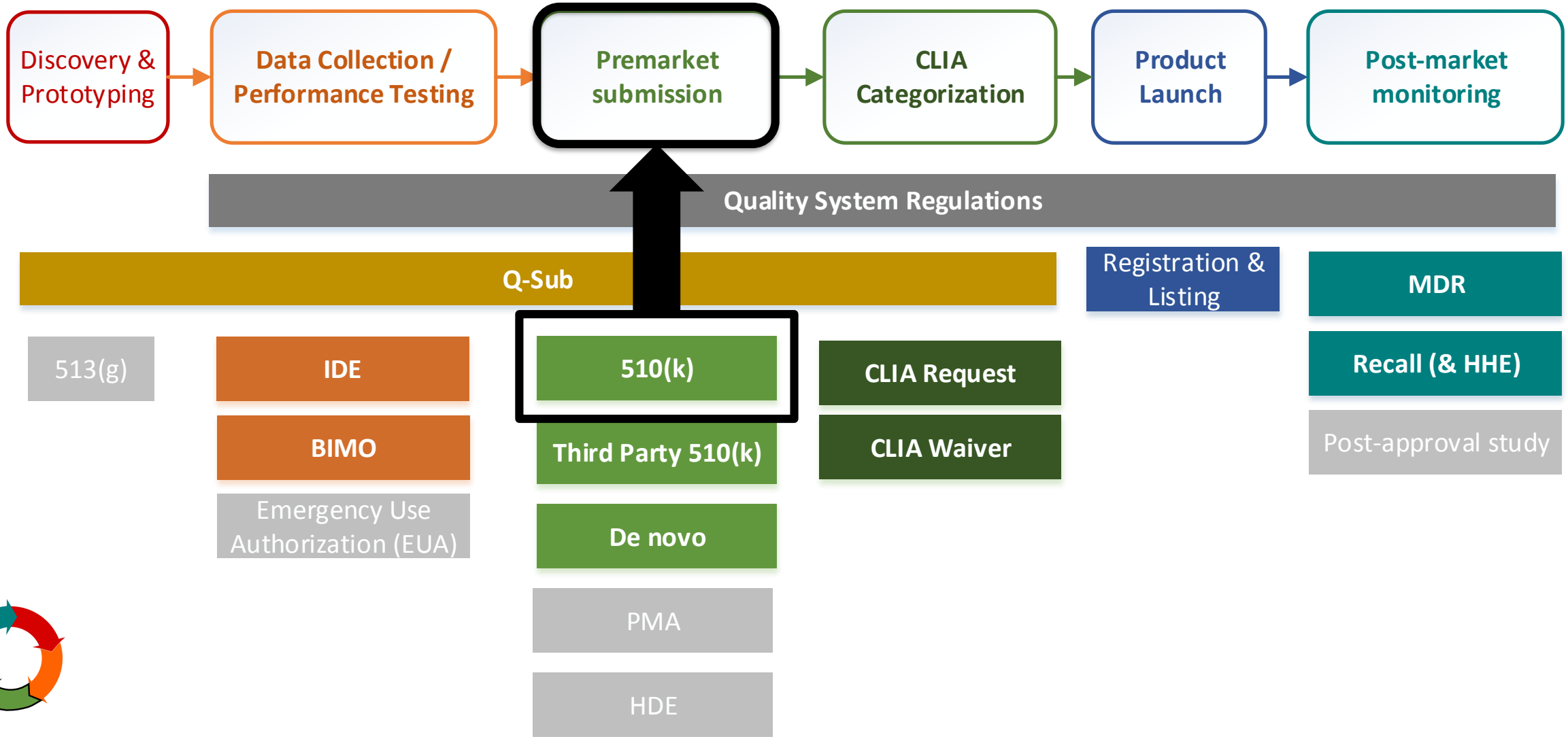
There are many regulatory activities throughout a device's life cycle



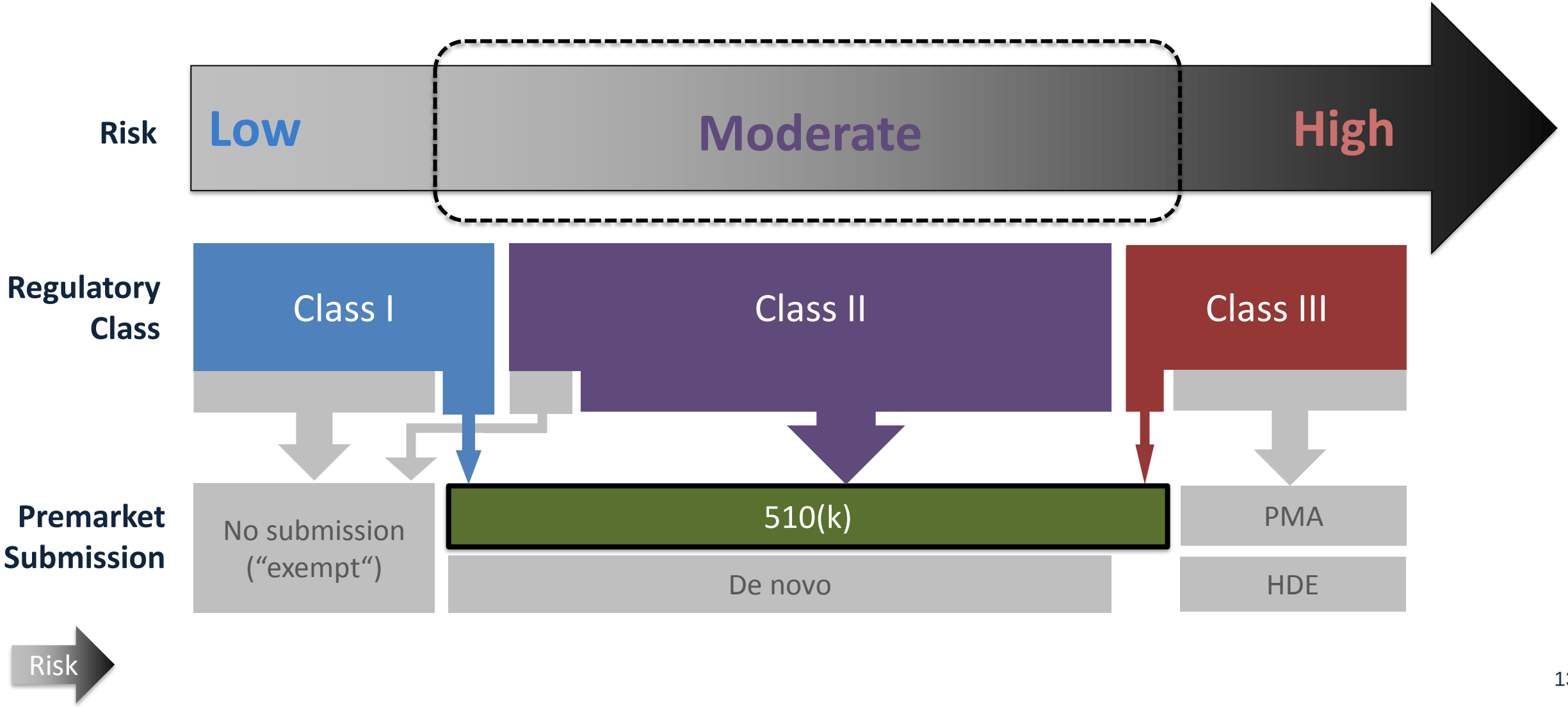
We will cover most regulatory activities in this workshop



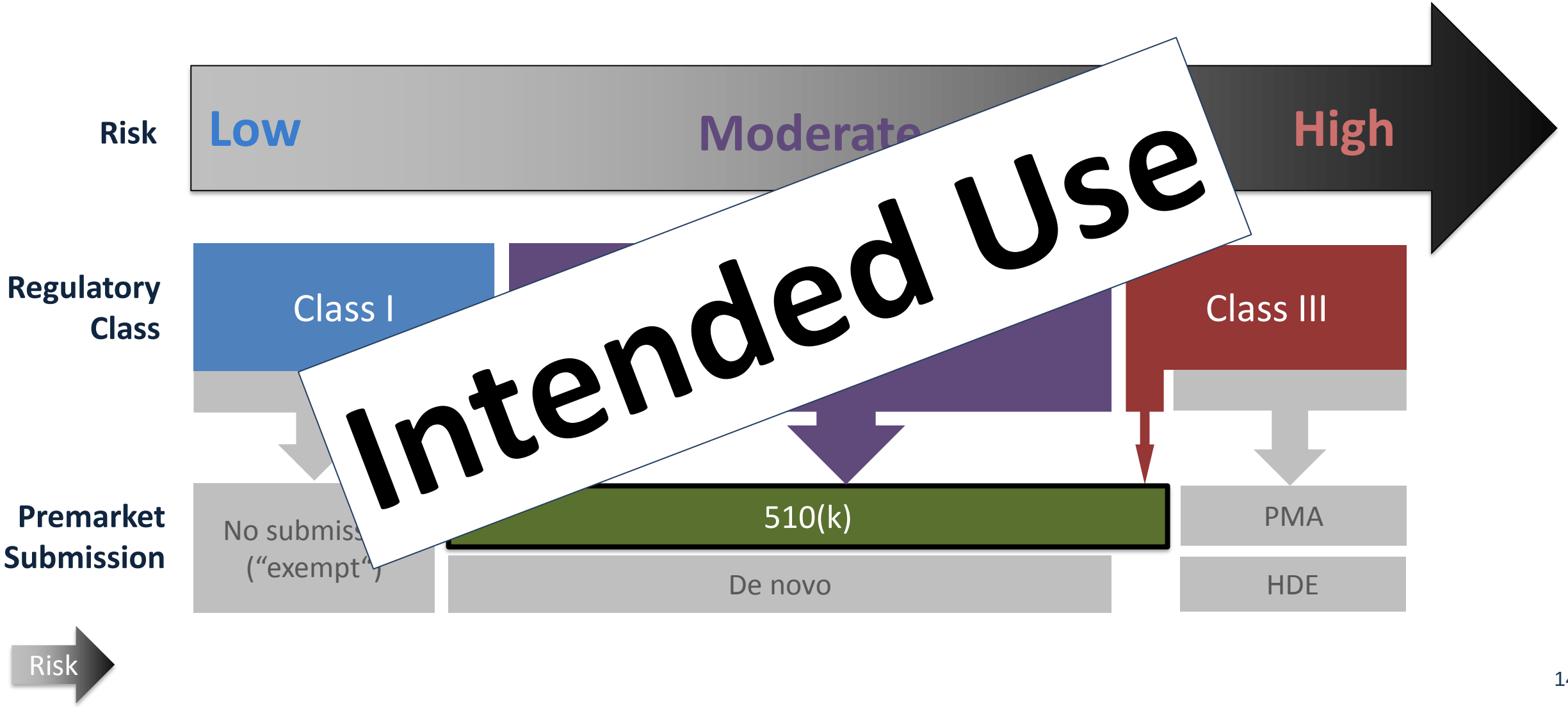
510(k) is one of several types of premarket submissions



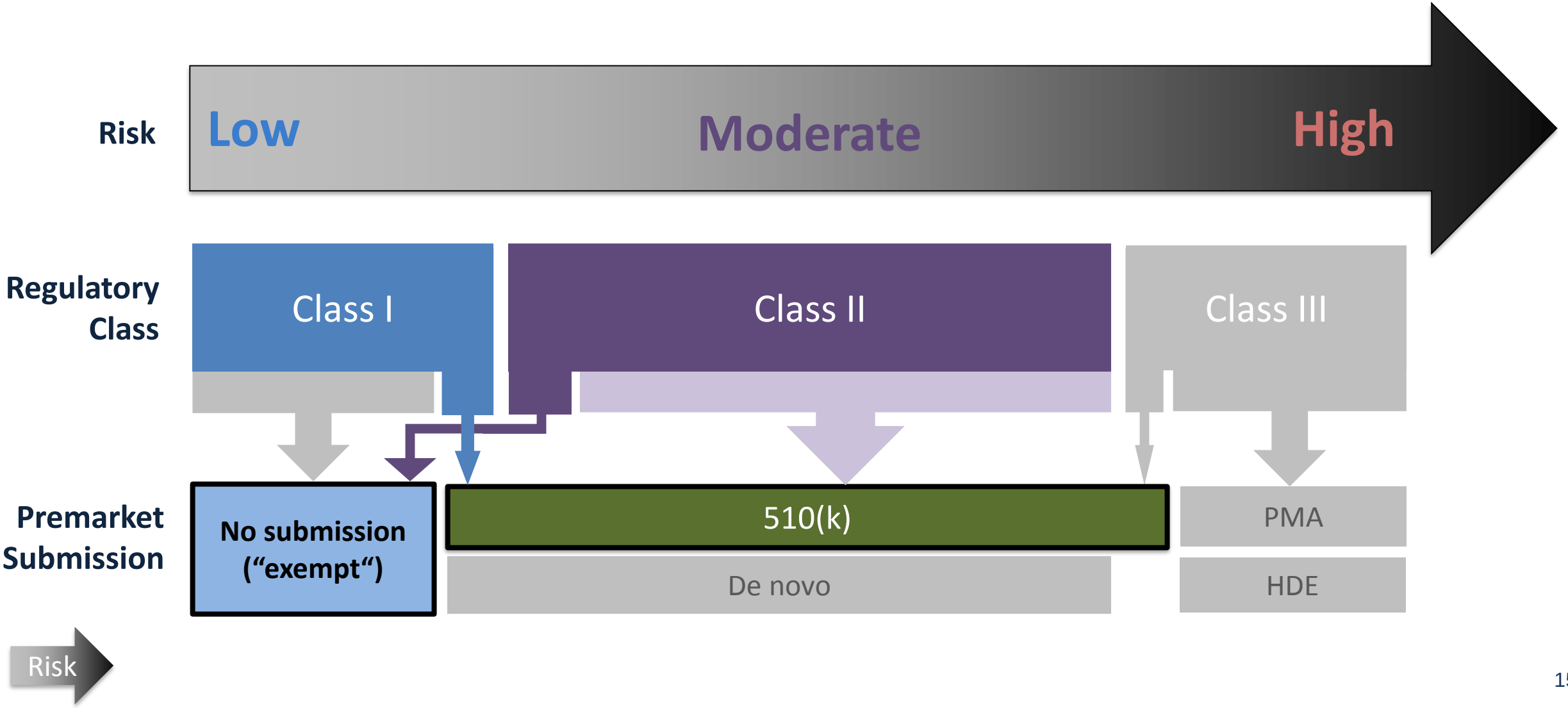
510(k)s are required for most moderate risk and some low & high risk devices



510(k)s are required for most moderate risk and some low & high risk devices



Some Class I devices require a 510(k), while some Class II devices do not



Some Class I devices require a 510(k) when exceed the "limitations of exemption"

Class I

Limitations of Exemption (21 CFR 8xx.9)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 862 -- CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
Subpart A--General Provisions

Sec. 862.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for

a) New intended use

b) Different fundamental scientific technology

c) Intended for certain IVD uses

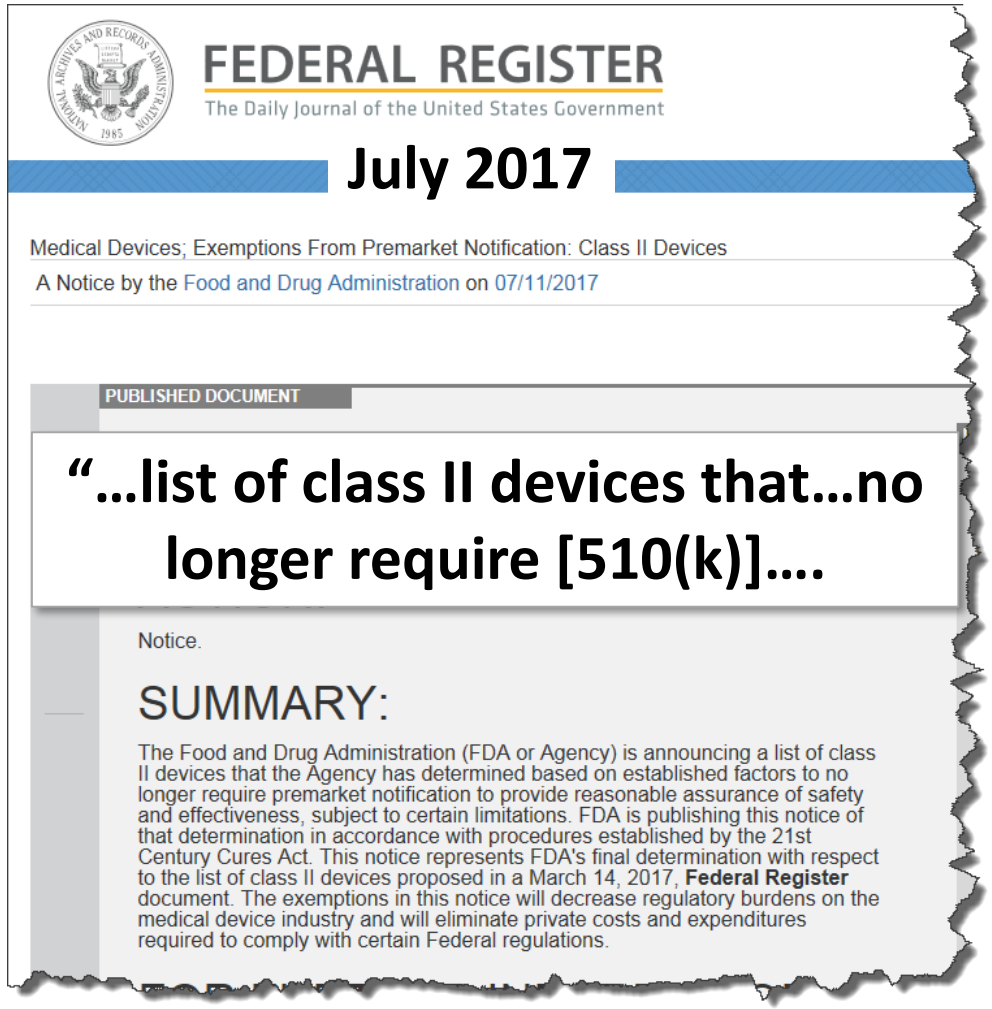
(4) For assessing the risk of cardiovascular diseases;
(5) For use in diabetes management;
(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
(8) For noninvasive testing as defined in 812.3(k) of this chapter; and
(9) For near patient testing (point of care).
[65 FR 2304, Jan. 14, 2000]

510(k)

Risk

Many IVD Class II devices no longer require a 510(k)

Class II



FEDERAL REGISTER
The Daily Journal of the United States Government

July 2017

Medical Devices; Exemptions From Premarket Notification: Class II Devices

A Notice by the Food and Drug Administration on 07/11/2017

PUBLISHED DOCUMENT

"…list of class II devices that…no longer require [510(k)]…."

Notice.

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing a list of class II devices that the Agency has determined based on established factors to no longer require premarket notification to provide reasonable assurance of safety and effectiveness, subject to certain limitations. FDA is publishing this notice of that determination in accordance with procedures established by the 21st Century Cures Act. This notice represents FDA's final determination with respect to the list of class II devices proposed in a March 14, 2017, **Federal Register** document. The exemptions in this notice will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations.

No Submission ("exempt")

Risk

Each premarket submission type has a review standard for assessing safety and effectiveness

Review Standard

Safety & Effectiveness

- 510(k)
- De novo
- PMA
- HDE

Unlike other submission types, 510(k) has a comparative review standard

Review Standard

Safety & Effectiveness

510(k) = **Comparative**
("substantially equivalent" to a "predicate")

De novo

PMA

HDE

= Stand-alone

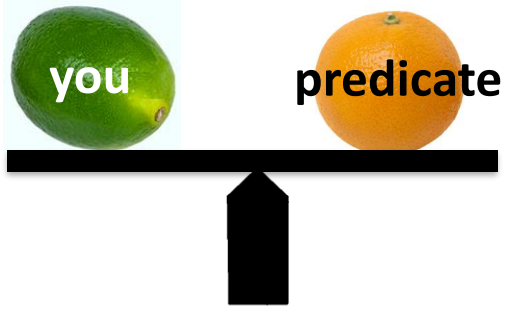
In 510(k), a device is compared to a predicate in two stages

Review Standard

Safety & Effectiveness

Stage 1: Is 510(k) appropriate?

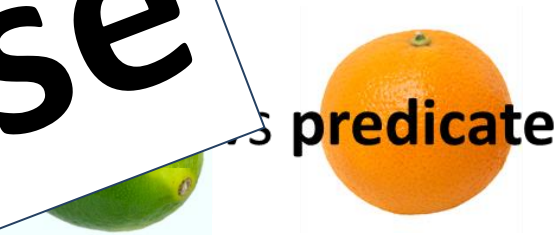
Stage 2: Does the data establish equivalence?



In 510(k), a device is compared to a predicate in two stages

Review Standard

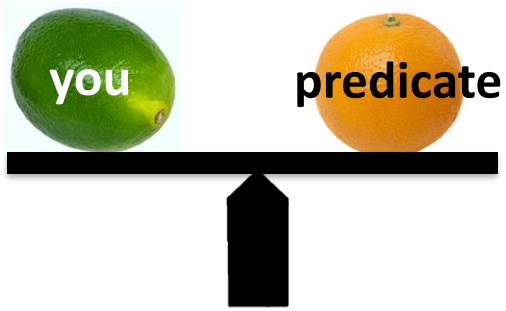
Stage 1: Is 510 ate?



Intended Use

Effe eness

2: Does the data establish equivalence?



The answer at each stage determines your regulatory path

Stage 1: Is 510(k) appropriate? → No → **Submit De novo, PMA or HDE** (NSE)

↓ Yes

Stage 2: Does the data establish equivalence? → No → **Submit new 510(k)** (NSE)

↓ Yes

Ok to market (SE)

Review Standard

Stage 1: To be a 510(k), a device needs an adequate predicate

510(k) is the right submission type when…

1.  = **predicate**

- ✓ Device legally marketed in U.S.
- ✓ Device does not require PMA

2. 

vs **predicate** 

- ✓ Not new intended use
- ✓ Different technological characteristics do **not** raise different questions of safety and effectiveness

Stage 1: To be a 510(k), a device needs an adequate predicate

510(k) is the right submission type when…

1.  = **predicate**

One Predicate Device

…rketed in U.S.
…es not require PMA

- ✓ Not new intended use
- ✓ Different technological characteristics do **not** raise different questions of safety and effectiveness

Stage 2: To be found SE, a device should be as safe and effective as the predicate

Primary predicate
(+ Reference devices)

Safety & Effectiveness

=

Your device

Performance Data

Descriptive Information

OR

Performance Data

Descriptive Info

Stage 2: To be found SE, a device should be as safe and effective as the predicate

Primary predicate
(+ Reference devices)

Your device

Safety & Effectiveness

=

Performance Data

Descriptive Info

Least Burdensome

Least Burdensome is defined by law and supported in MDUFA IV

Least Burdensome

21st Century Cures Act

Request only "minimum required information" for decision

Do not change standards "for premarket approval" or "substantial equivalence"

"consider the role of postmarket information"

MDUFA IV Commitment Letter

Deficiency letters will…

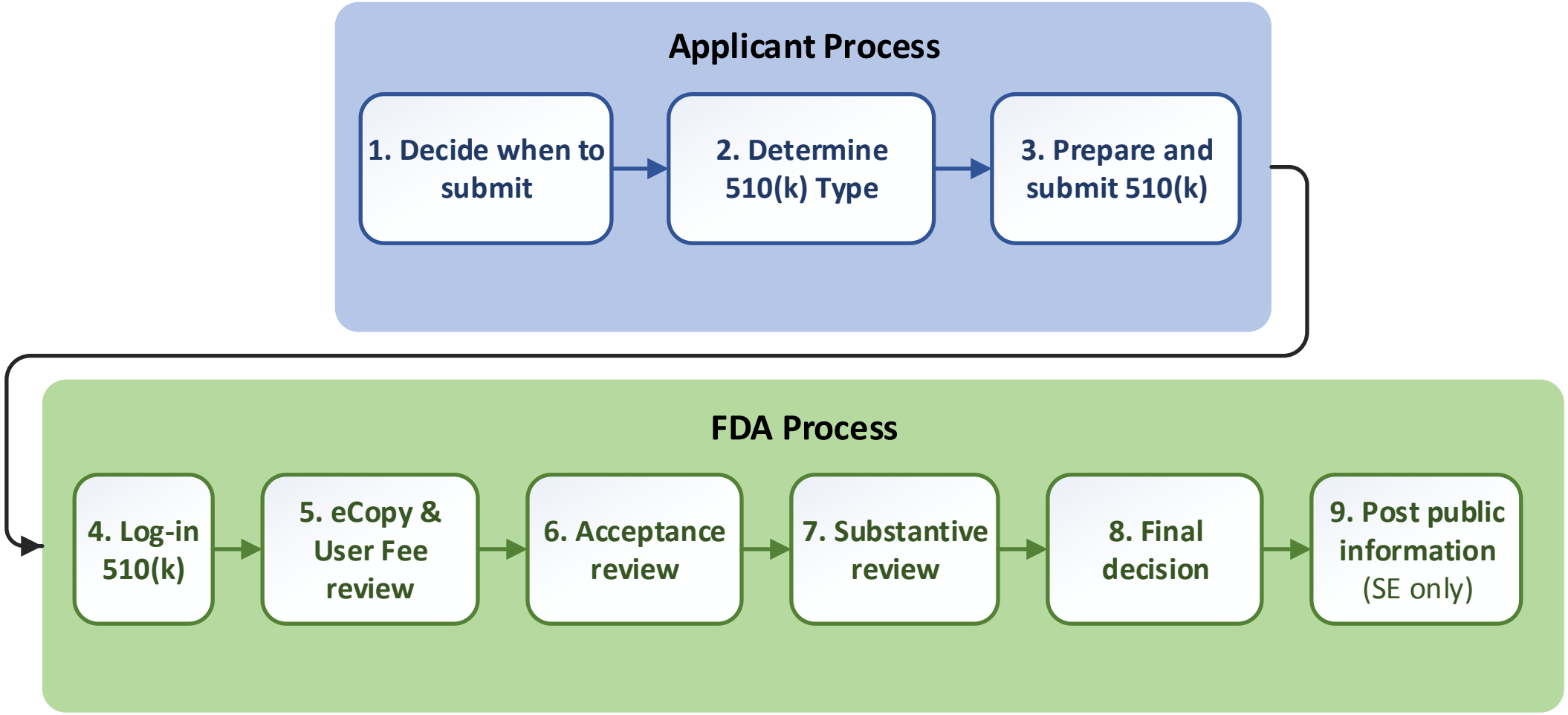
"…include a statement of the basis for the deficiencies.."

"…ensure the deficiencies cited are relevant to [SE]"

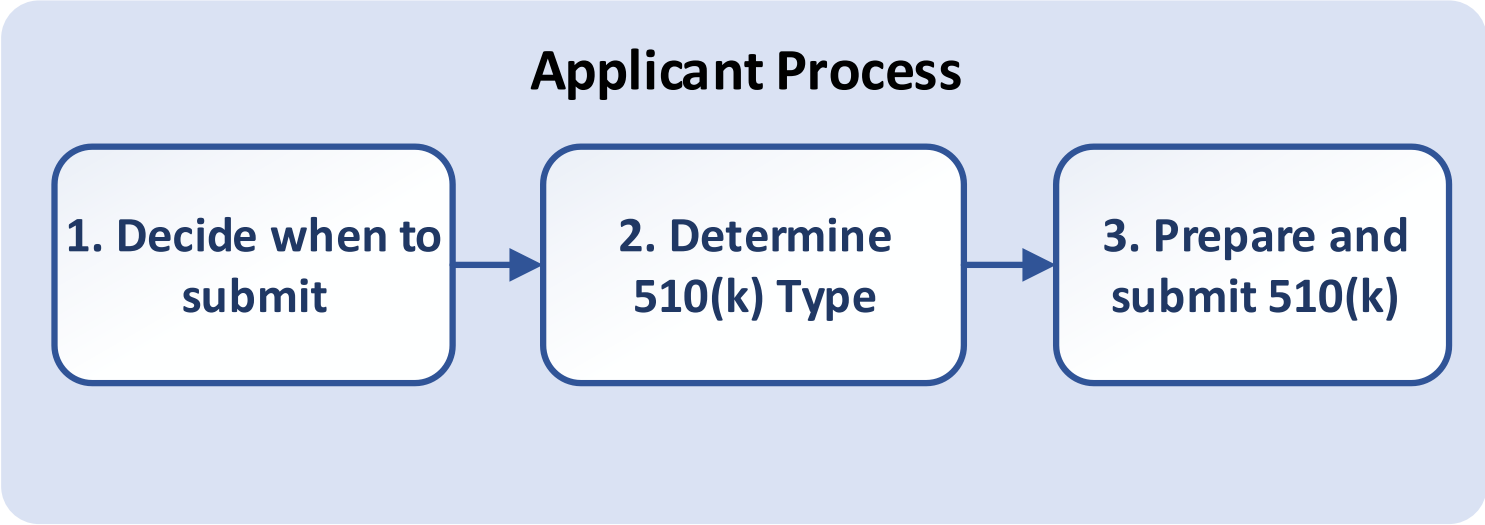
Understanding 510(k) begins with three key concepts

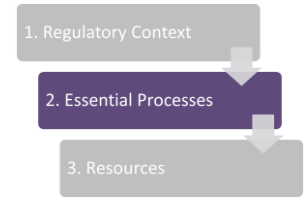
1. Regulatory Context
2. Essential Processes
3. Resources

510(k)s have processes for both applicants and FDA



The applicant's 510(k) process includes three important steps





A new 510(k) is required for new and modified devices

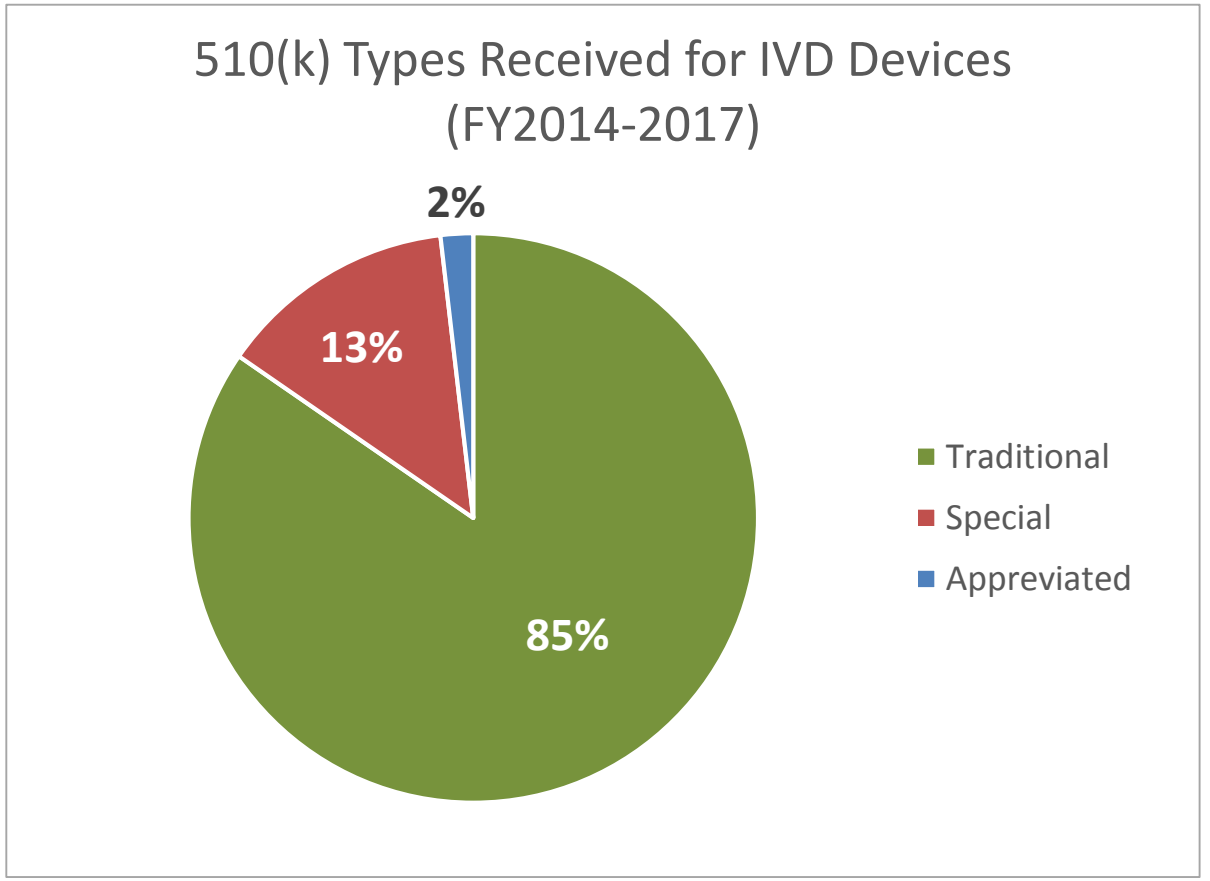
A 510(k) is required when:

- Introducing device to U.S. market for the first time
- New or different intended use
- Device modification that “could significantly affect safety or effectiveness”

There are three types of 510(k)s; Traditional is most common

2. Determine 510(k) Type

Traditional	• Most common • Review all relevant performance data
Special	• Certain changes • Rely on summary of results from design control process
Abbreviated	• Rely on conformance to guidance documents, special controls, and/or recognized standards



Source: Internal data

3. Prepare and submit 510(k)

510(k)s should be complete and high quality

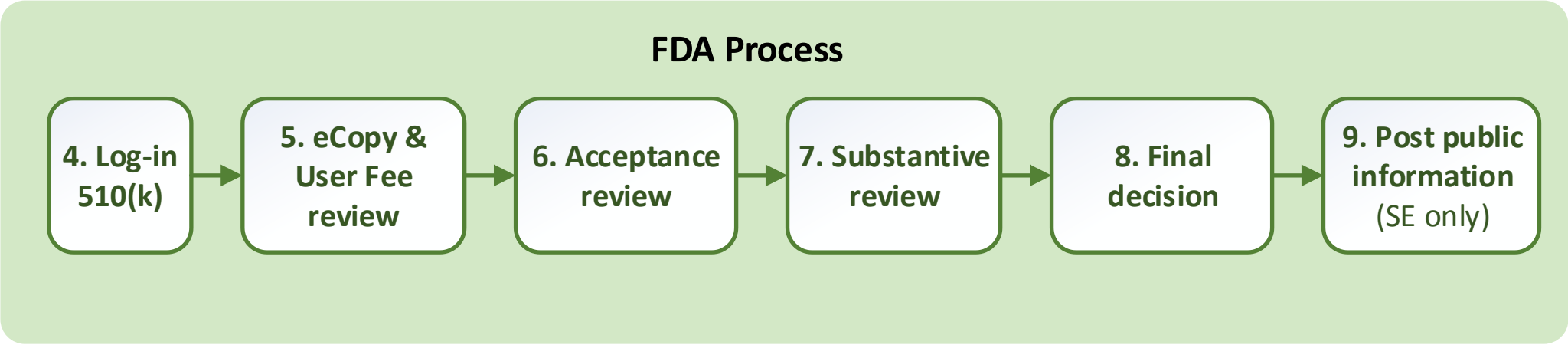
Complete

- ✓ Contact info
- ✓ Primary predicate
- ✓ RTA checklist elements
- ✓ eCopy
- ✓ User Fee

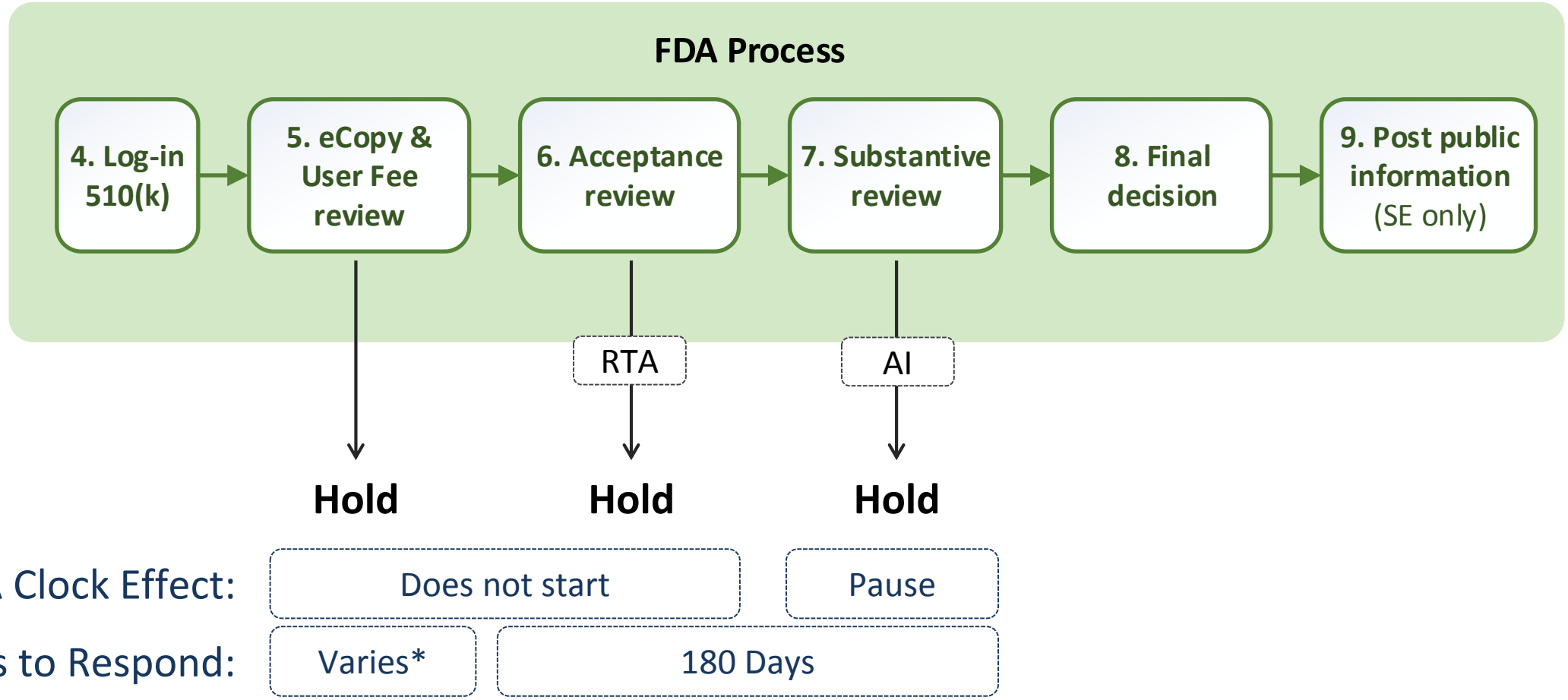
Quality

- Organized
- Consistent
- Purposeful
- Tell the story of equivalence

FDA's 510(k) process includes six important steps

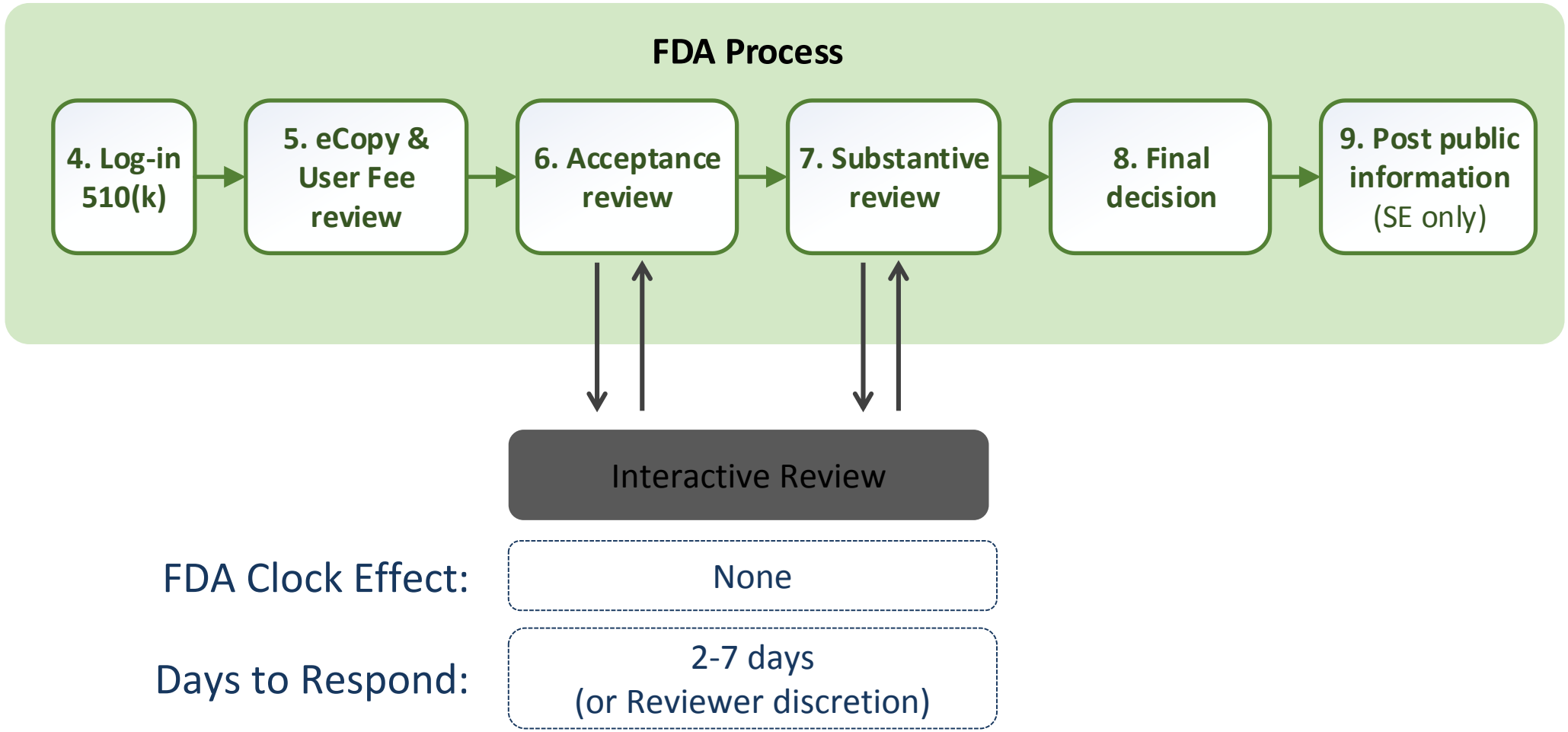


FDA's 510(k) process is subject to "Hold"

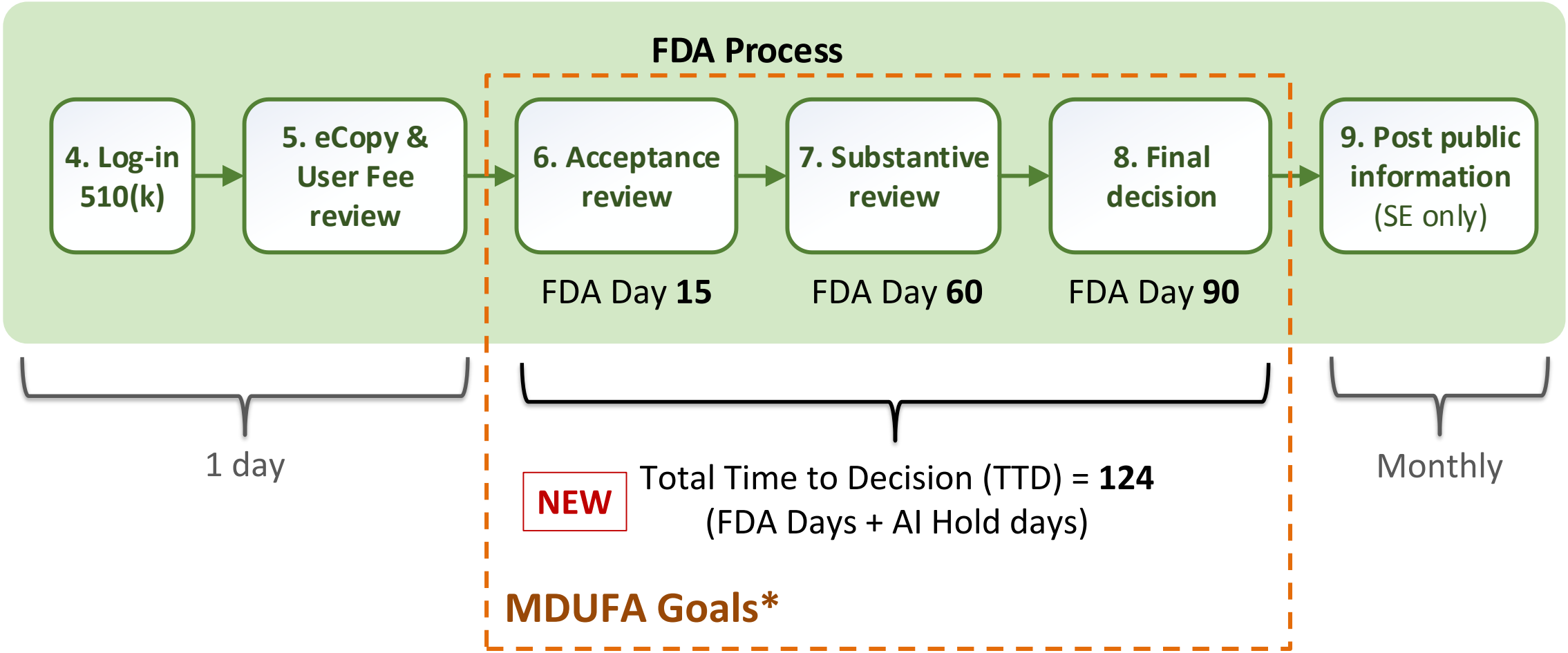


**Depends on whether Original or response to RTA or AI hold*

FDA's 510(k) process is interactive

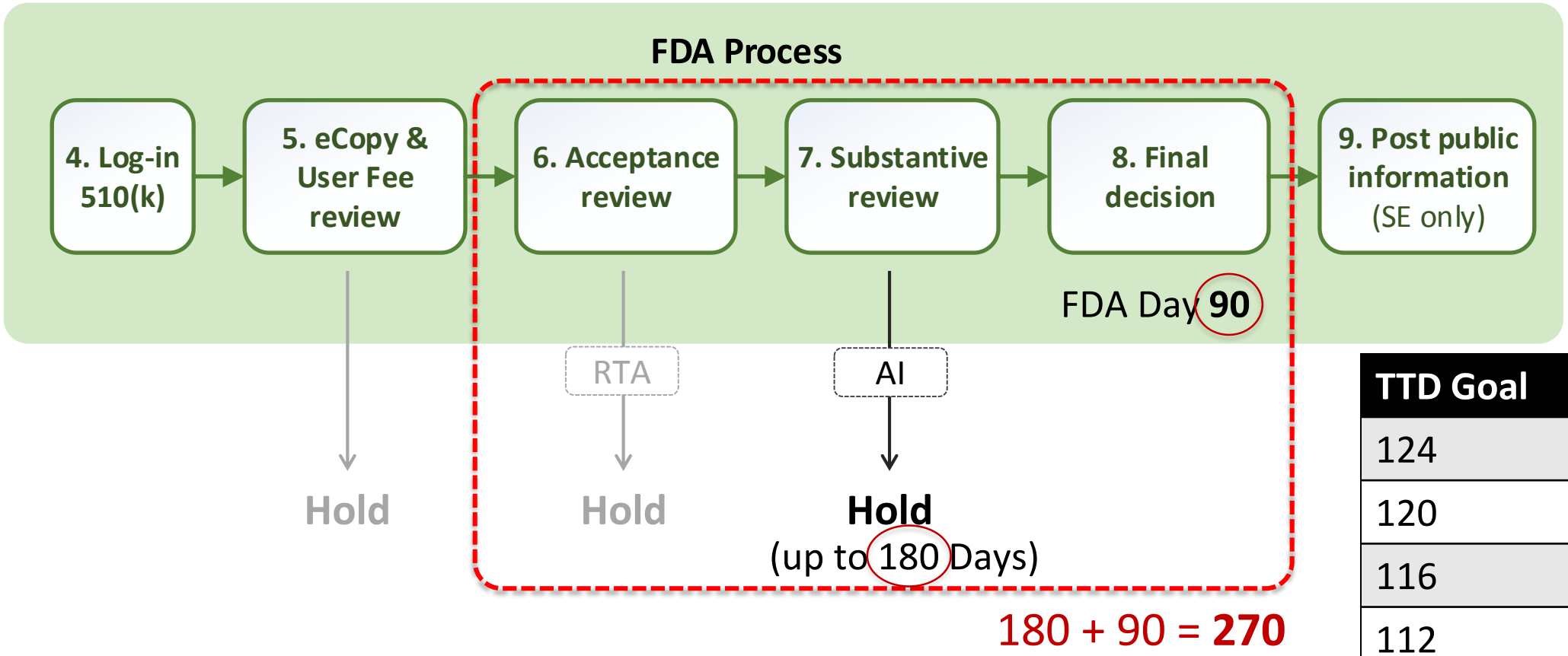


FDA's 510(k) process is subject to MDUFA and other goals



*Refer to MDUFA IV Commitment Letter for percent of submissions that should meet each goal

Total Time to Decision (TTD) goals are a shared responsibility

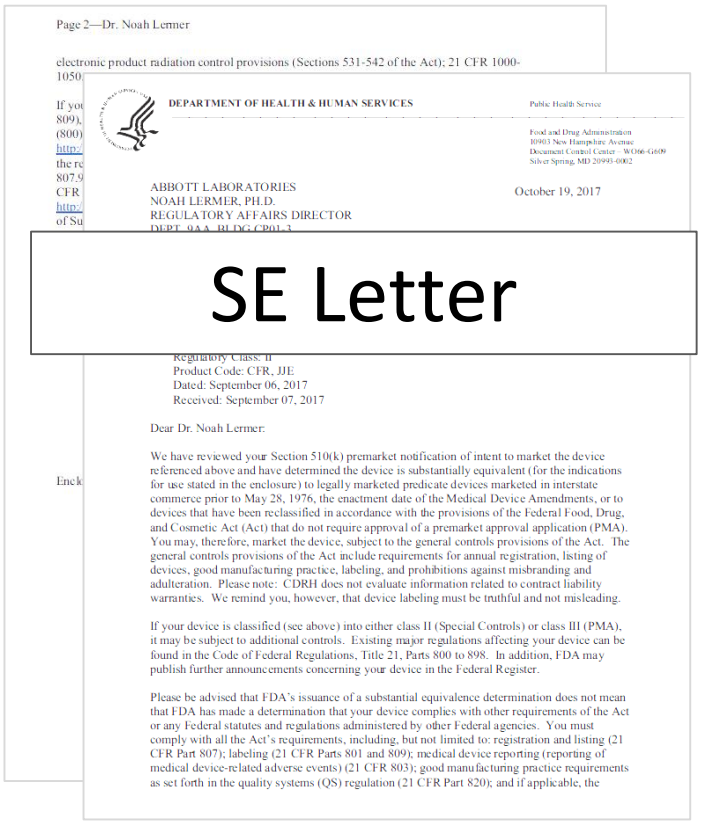


TTD Goal	Fiscal Year
124	2018
120	2019
116	2020
112	2021
108	2022

MDUFA IV Commitment Letter: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf

8. Final decision

After an SE decision, you will receive three documents


Page 2—Dr. Noah Lerner

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

ABBOTT LABORATORIES
NOAH LERMER, PH.D.
REGULATORY AFFAIRS DIRECTOR

October 19, 2017

Regulatory Class: II
Product Code: CFR, JJE
Dated: September 06, 2017
Received: September 07, 2017

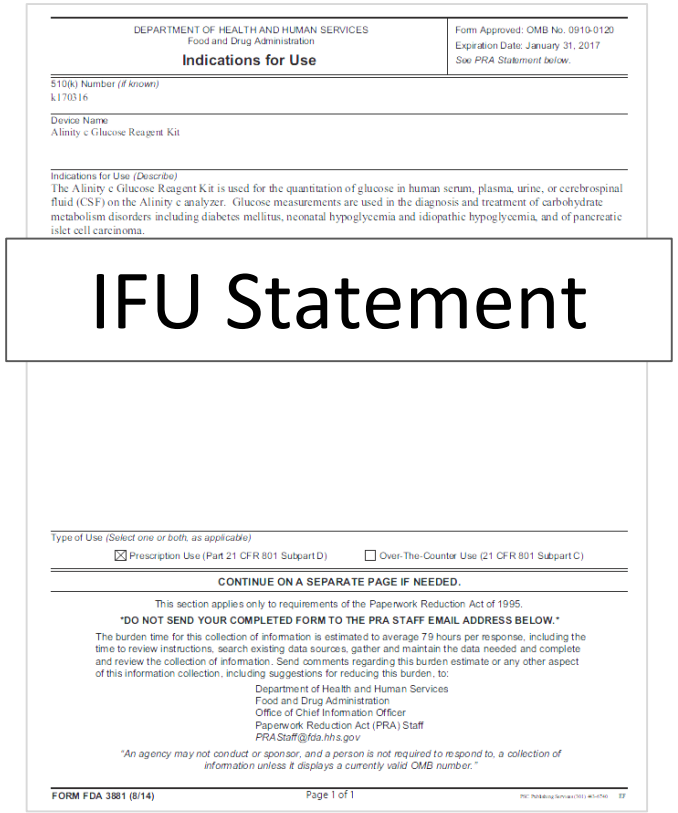
Dear Dr. Noah Lerner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

SE Letter


DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number *(if known)*
k170316

Device Name
Alinity c Glucose Reagent Kit

Indications for Use *(Describe)*
The Alinity c Glucose Reagent Kit is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the Alinity c analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Type of Use *(Select one or both, as applicable)*
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

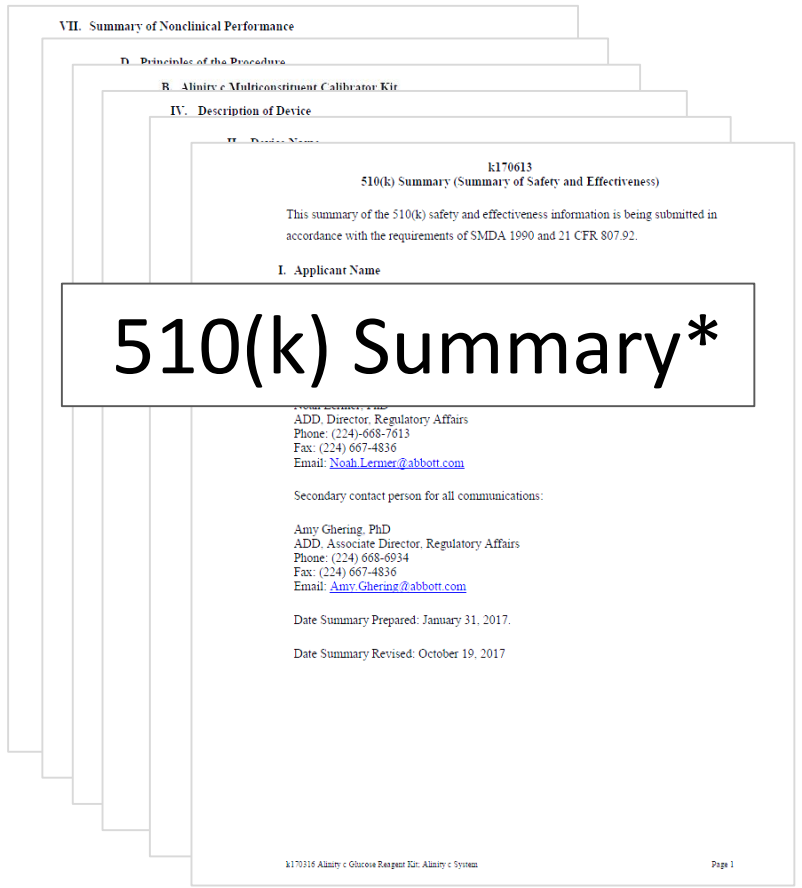
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1

IFU Statement


VII. Summary of Nonclinical Performance

D. Principles of the Procedure

B. Alinity c Multiconstituent Calibrator Kit

IV. Description of Device

k170613
510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Applicant Name

ADD. Director, Regulatory Affairs
Phone: (224)-668-7613
Fax: (224) 667-4836
Email: Noah.Lerner@abbott.com

Secondary contact person for all communications:

Amy Ghering, PhD
ADD. Associate Director, Regulatory Affairs
Phone: (224) 668-6934
Fax: (224) 667-4836
Email: Amy.Ghering@abbott.com

Date Summary Prepared: January 31, 2017.

Date Summary Revised: October 19, 2017

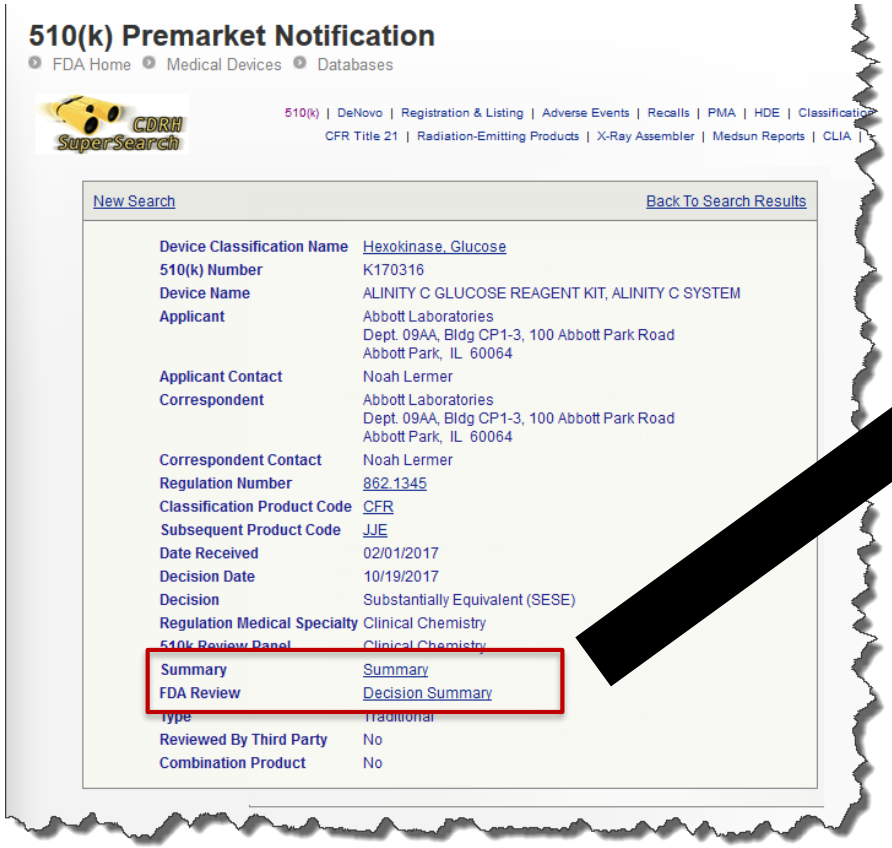
k170316 Alinity c Glucose Reagent Kit; Alinity c System Page 1

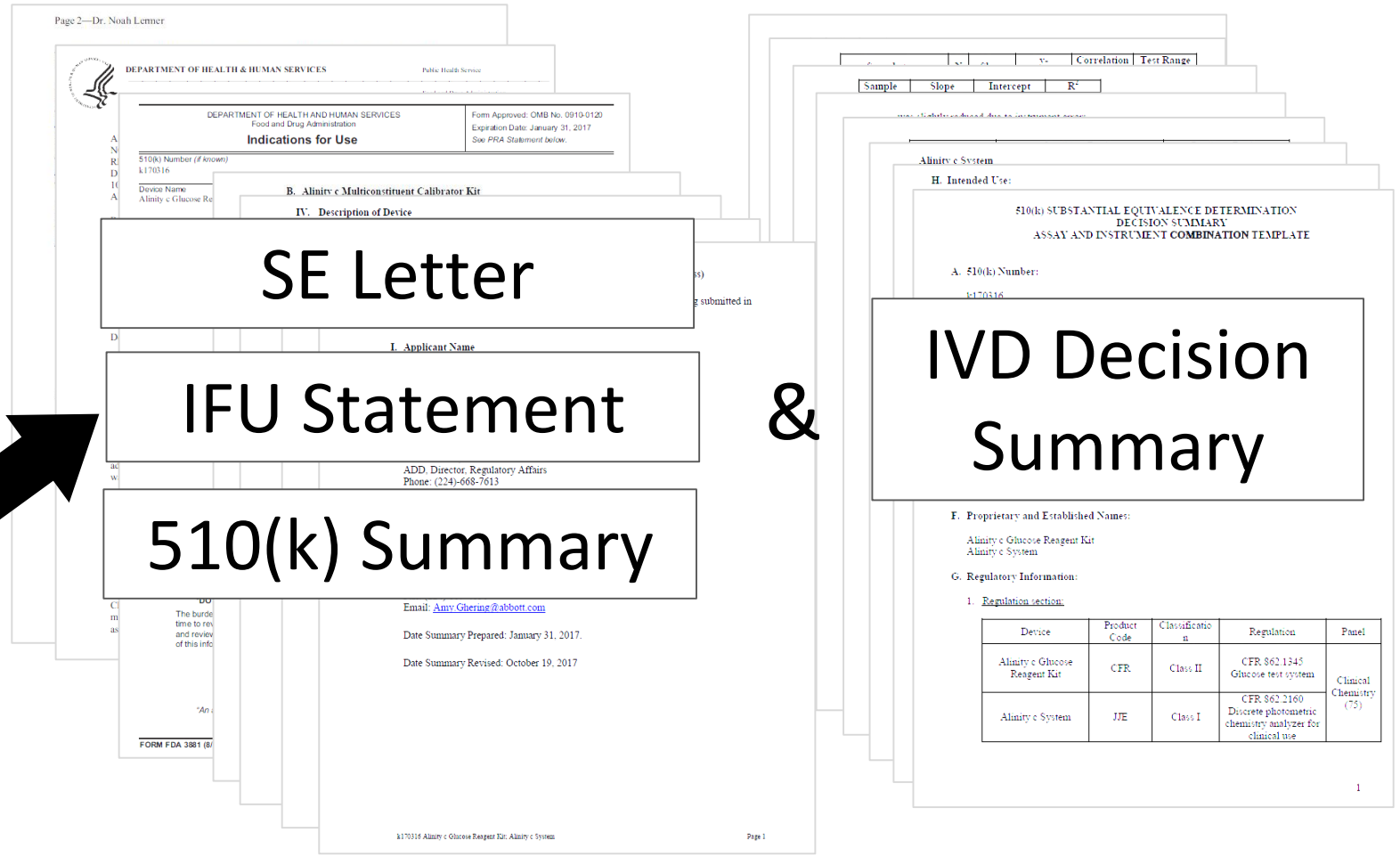
510(k) Summary*

**Except if you provide a 510(k) Statement*

After an SE decision, we will publicly post four documents

9. Post public information (SE only)



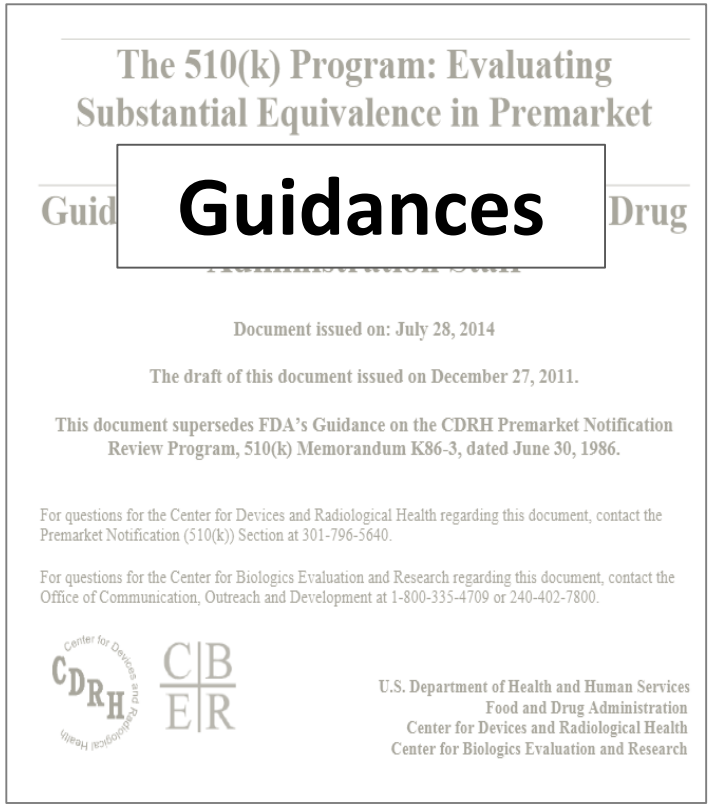


Public 510(k) Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Understanding 510(k) begins with three key concepts

1. Regulatory Context
2. Essential Processes
3. Resources

Resources are available to help



The 510(k) Program: Evaluating Substantial Equivalence in Premarket

Guid … Drug … Administration Staff

Guidances

Document issued on: July 28, 2014

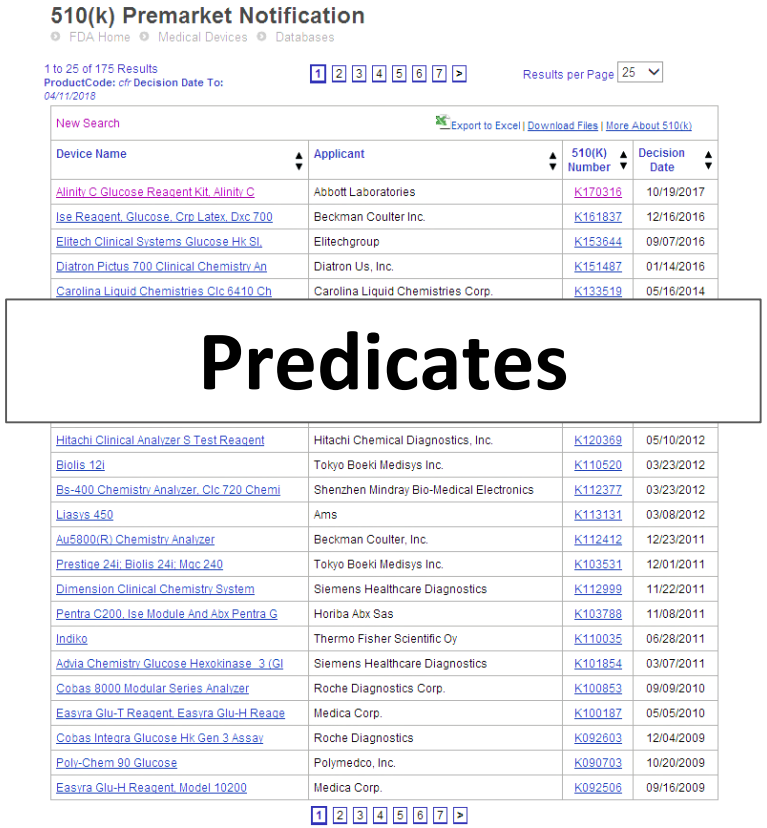
The draft of this document issued on December 27, 2011.

This document supersedes FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.

For questions for the Center for Devices and Radiological Health regarding this document, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research



510(k) Premarket Notification

FDA Home · Medical Devices · Databases

1 to 25 of 175 Results
ProductCode: cfr Decision Date To: 04/11/2018

1 2 3 4 5 6 7 >

Results per Page 25

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Alinity C Glucose Reagent Kit, Alinity C	Abbott Laboratories	K170316	10/19/2017
Ise Reagent, Glucose, Crp Latex, Dxc 700	Beckman Coulter Inc.	K161837	12/16/2016
Elitech Clinical Systems Glucose Hk Sl	Elitechgroup	K153644	09/07/2016
Diatron Pictus 700 Clinical Chemistry An	Diatron Us, Inc.	K151487	01/14/2016
Carolina Liquid Chemistries Clc 6410 Ch	Carolina Liquid Chemistries Corp.	K133519	05/16/2014
Hitachi Clinical Analyzer S Test Reagent	Hitachi Chemical Diagnostics, Inc.	K120369	05/10/2012
Biolis 12i	Tokyo Boeki Medisys Inc.	K110520	03/23/2012
Bs-400 Chemistry Analyzer, Clc 720 Chemi	Shenzhen Mindray Bio-Medical Electronics	K112377	03/23/2012
Liasys 450	Ams	K113131	03/08/2012
Au5800(R) Chemistry Analyzer	Beckman Coulter, Inc.	K112412	12/23/2011
Prestige 24i; Biolis 24i; Mqc 240	Tokyo Boeki Medisys Inc.	K103531	12/01/2011
Dimension Clinical Chemistry System	Siemens Healthcare Diagnostics	K112999	11/22/2011
Pentra C200, Ise Module And Abx Pentra G	Horiba Abx Sas	K103788	11/08/2011
Indiko	Thermo Fisher Scientific Oy	K110035	06/28/2011
Advia Chemistry Glucose Hexokinase_3 (Gl	Siemens Healthcare Diagnostics	K101854	03/07/2011
Cobas 8000 Modular Series Analyzer	Roche Diagnostics Corp.	K100853	09/09/2010
Easyra Glu-T Reagent, Easyra Glu-H Reage	Medica Corp.	K100187	05/05/2010
Cobas Integra Glucose Hk Gen 3 Assay	Roche Diagnostics	K092603	12/04/2009
Poly-Chem 90 Glucose	Polymedco, Inc.	K090703	10/20/2009
Easyra Glu-H Reagent, Model 10200	Medica Corp.	K092506	09/16/2009

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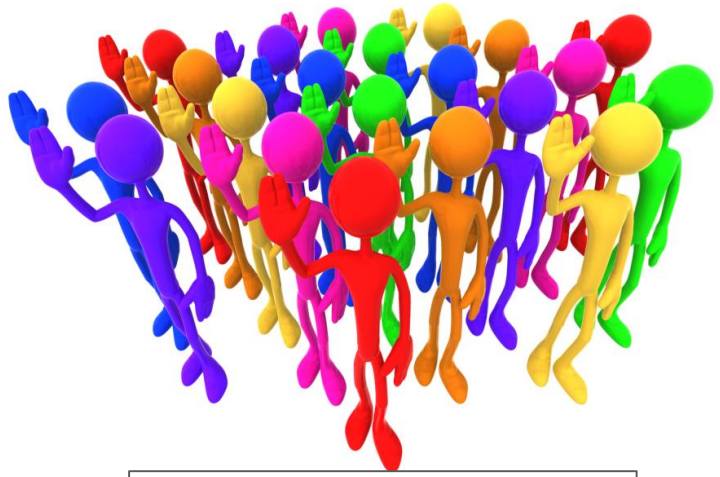
Predicates

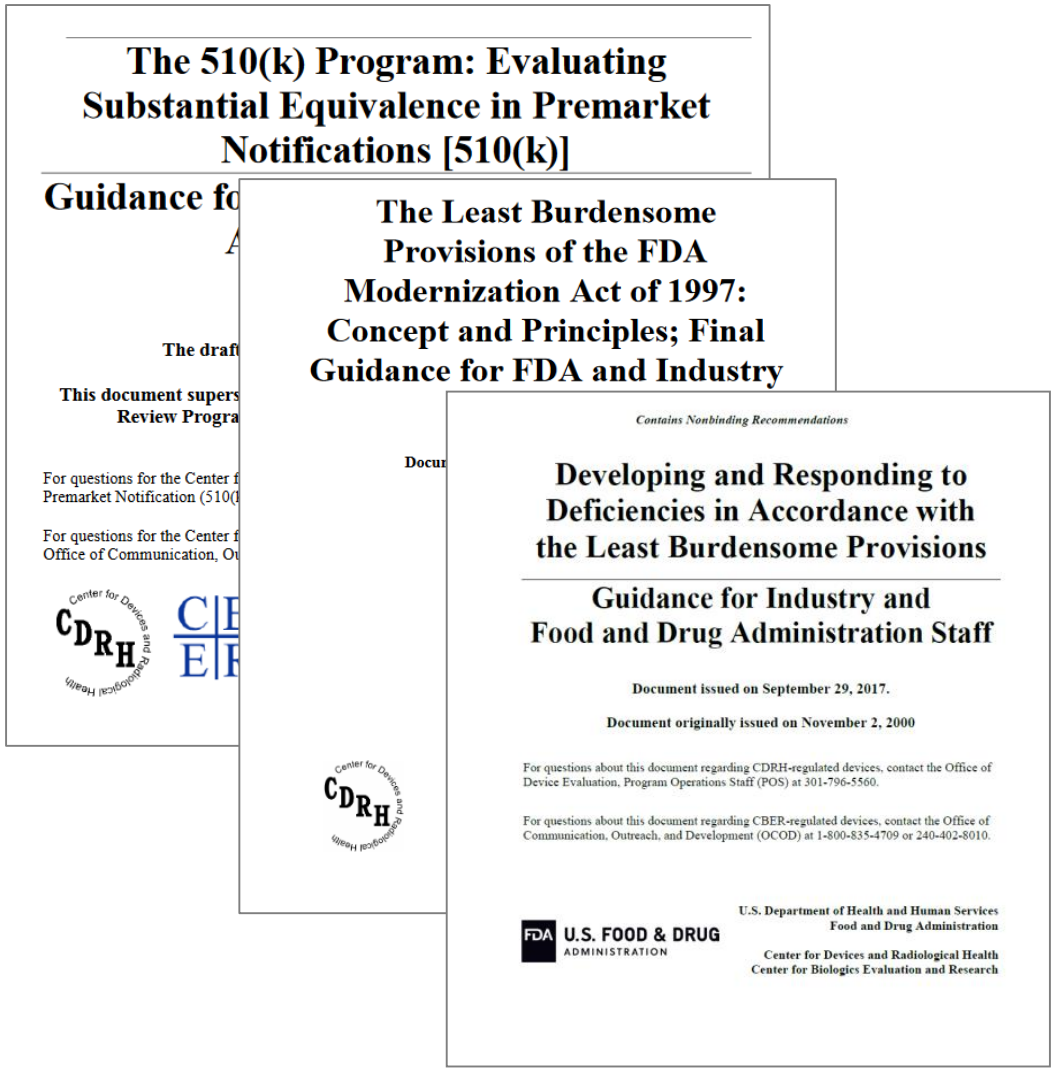


People

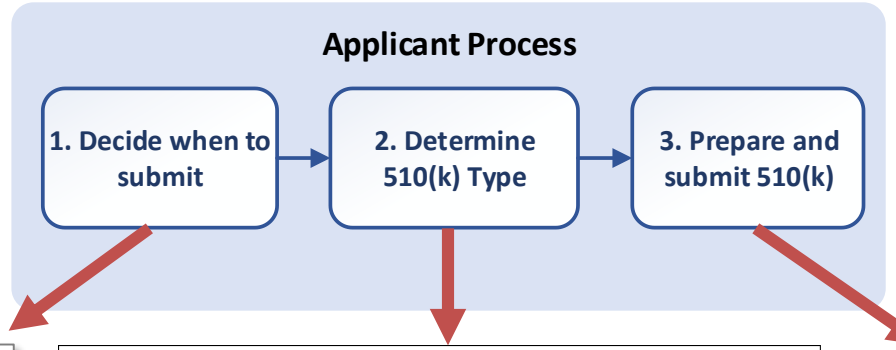
There are guidances related to the 510(k) review standard

Review Standard

Compared to a predicate



There are guidances related to the applicant's 510(k) processes



Deciding When to Submit a 510(k) for a Change to an Existing Device

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

For questions about this document, contact (CDRH) Linda Ricci, Office of Device Evaluation, 301-796-6325, Linda.Ricci@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

The New 510(k) Paradigm

Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications

Final Guidance

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Prepared by the
Center for Devices and Radiological Health

March 20, 1998

Comments and suggestions may be submitted at any time for Agency consideration to Heather Rosecrans, Office of Device Evaluation, 10903 New Hampshire Avenue, Silver Spring, MD 20993. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact the Premarket Notification (510(k)) Section at 301-796-5640.

Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff

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Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: January 30, 2018

Document originally issued on May 20, 1994

This document supersedes "Refuse to Accept Policy for 510(k)s" issued August 4, 2015.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

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U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

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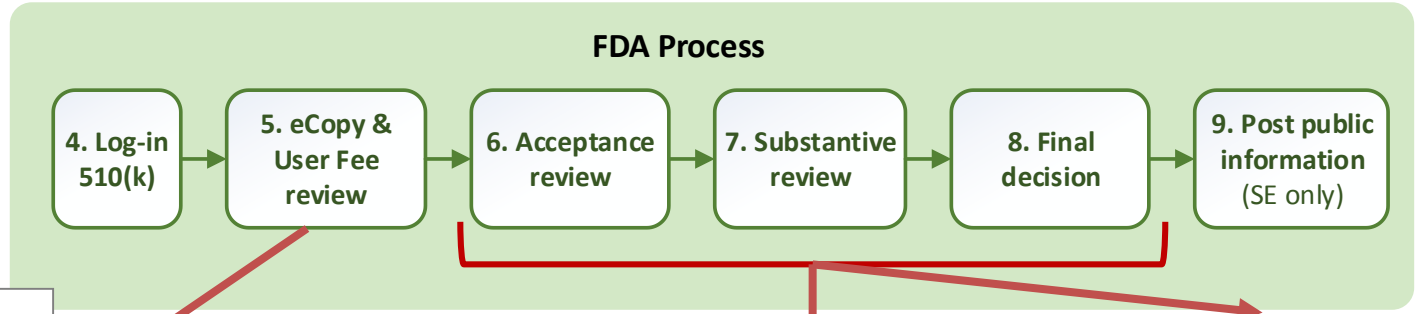
There are guidances related to FDA's 510(k) processes



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

eCopy Program for Medical Device Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 3, 2015.

This document supersedes the guidance of the same title dated October 10, 2013.

For questions regarding this document, contact CDRH's eCopy Program Coordinators at 240-402-3717 or cdrh-eCopyinfo@fda.hhs.gov or CBER's Office of Communication, Outreach and Development, at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
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Types of Communication During the Review of Medical Device Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 4, 2014

This document supersedes "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" dated February 28, 2008.

The draft of this document was issued on April 5, 2013.

For questions regarding this document, contact the Premarket Notification (510(k)) Section or the Premarket Approval (PMA) Section of CDRH at 301-796-5640 or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 2, 2017.

Document originally issued on May 21, 2004.

This document supersedes "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" issued October 15, 2012.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Program at (301) 796-5640, or by email to 510k_program@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
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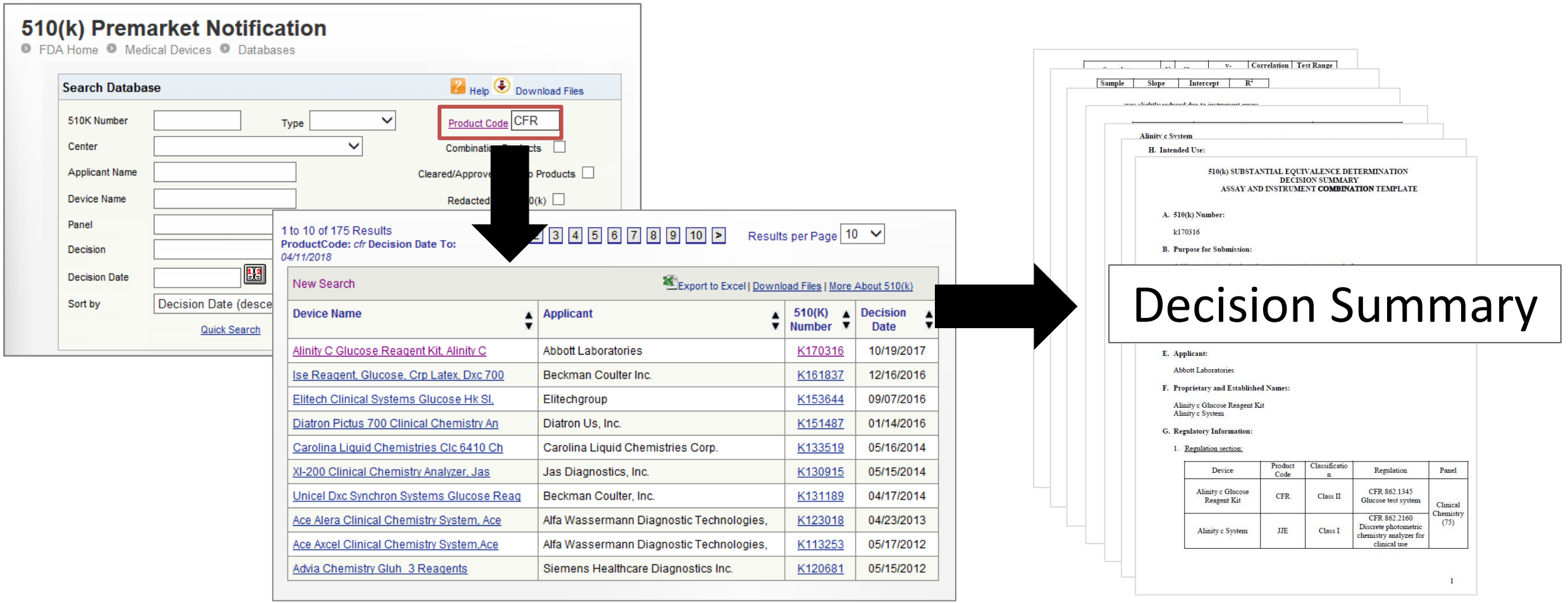
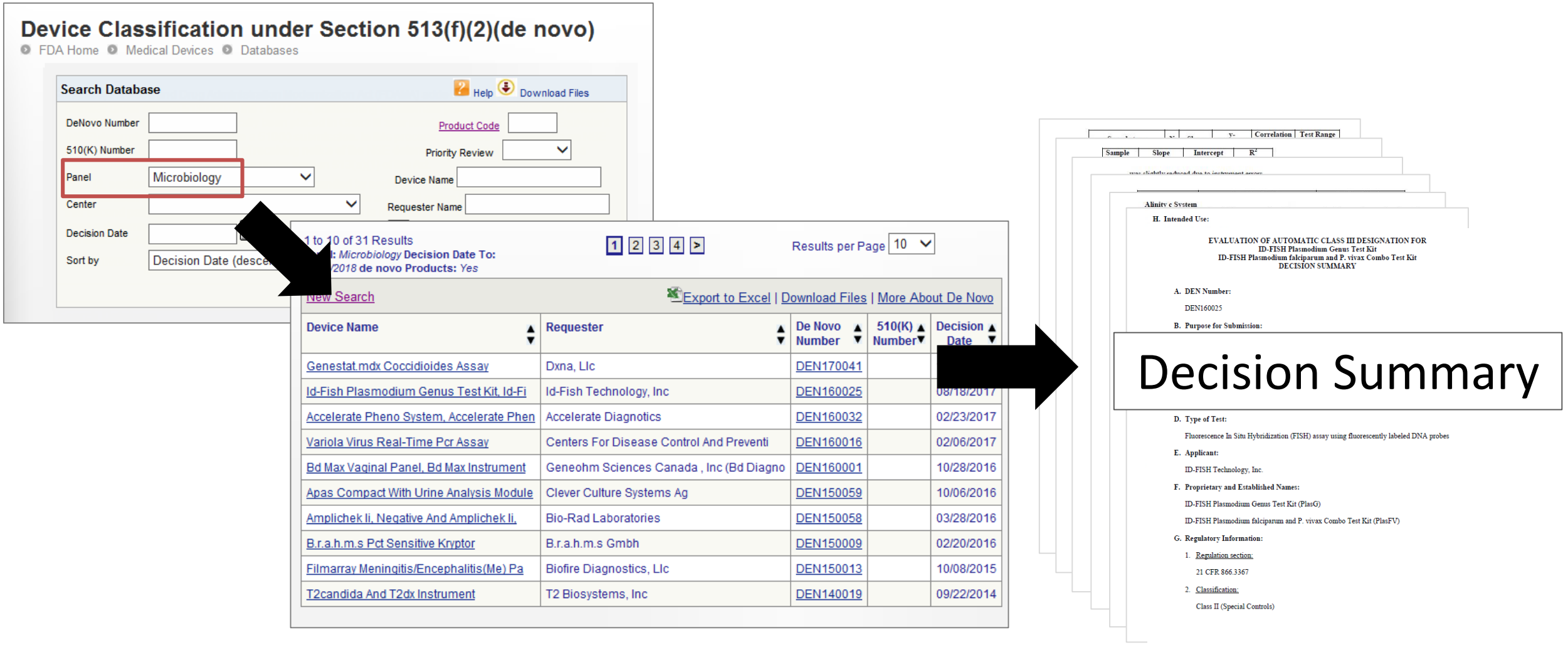
Reviewing predicate 510(k)s and Decision Summaries can help



Public 510(k) Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Reviewing predicate De novos and Decision Summaries can help



Public De novo Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

For all types of questions, we can help

Type of Question

General → Specific

Division of Industry and Consumer Education
DICE@fda.hhs.gov

510(k) Program Staff
510k_Program@fda.hhs.gov

Review Staff
Pre-Submission,
Interactive Review

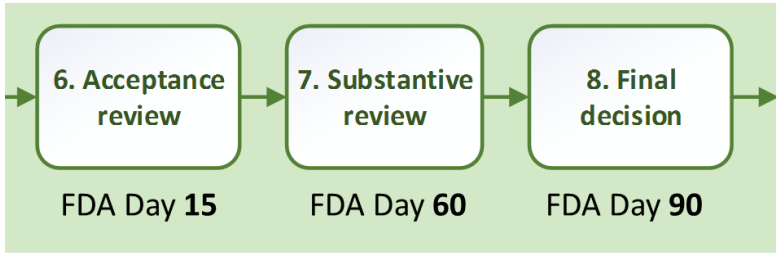
There's a lot to know about 510(k)s, and it can be difficult to know where to begin

FDA shares AMDM's commitment to industry education

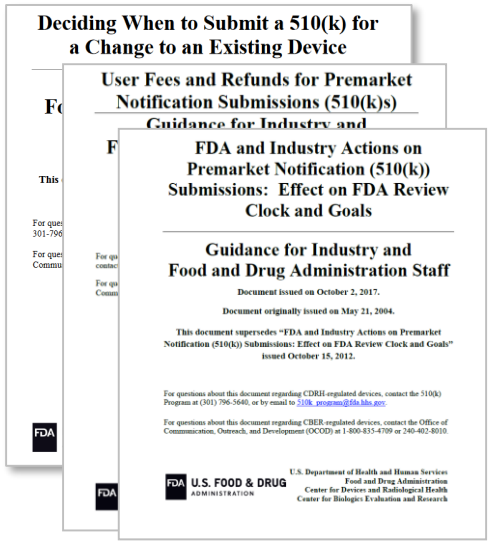
Understanding 510(k)s begins with three key concepts

1. Regulatory Context

2. Essential Processes



3. Resources



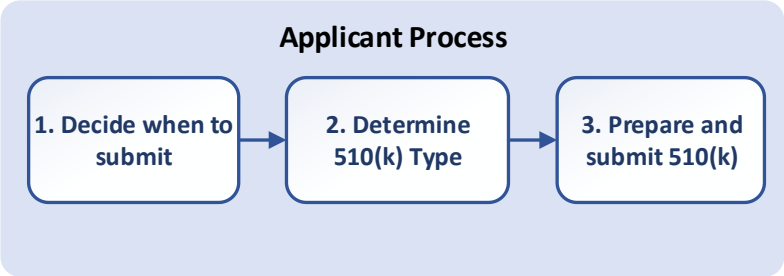
QUESTIONS AND DISCUSSION

APPENDIX

510(k) Guidance Links

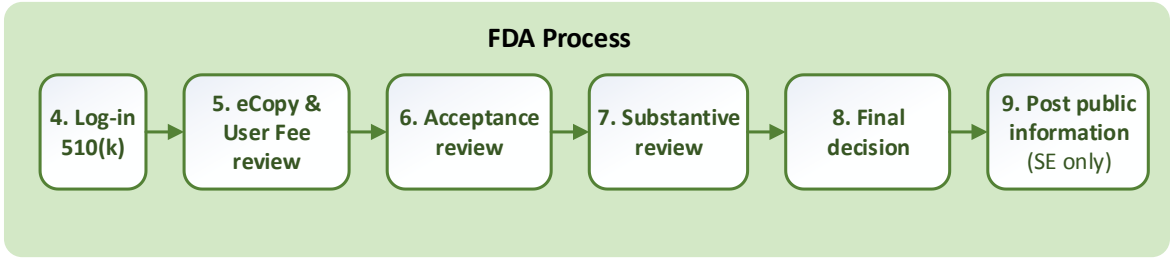
- **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284443.pdf)
- **The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles** (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085999.pdf)
- **Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions** (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf)

510(k) Guidance Links (cont'd)



- **Deciding When to Submit a 510(k) for a Change to an Existing Device** (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm514771.pdf)
- **Deciding When to Submit a 510(k) for a Software Change to an Existing Device** (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.pdf)
- **The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications** (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf)
- **Refuse to Accept Policy for 510(k)s** (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf)
- **Format for Traditional and Abbreviated 510(k)s"** (http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm)

510(k) Guidance Links (cont'd)



- **eCopy Program for Medical Device Submissions** (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf)
- **User Fees and Refunds for Premarket Notification Submissions (510(k)s** (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345931.pdf)
- **Types of Communication During the Review of Medical Device Submissions** (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM341948.pdf)
- **FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals** (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089738.pdf)

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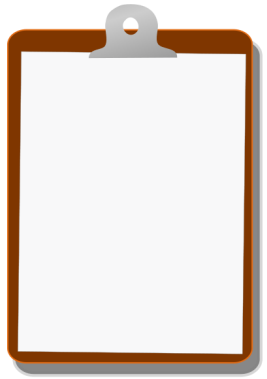

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