

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

AMDM OIR Submissions Workshop  
April 16, 2018

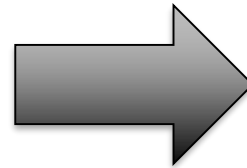
Sara Aguel, Policy Analyst  
OIR/DPOM

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

1976



*President Gerald Ford signs the Medical Device Amendments*

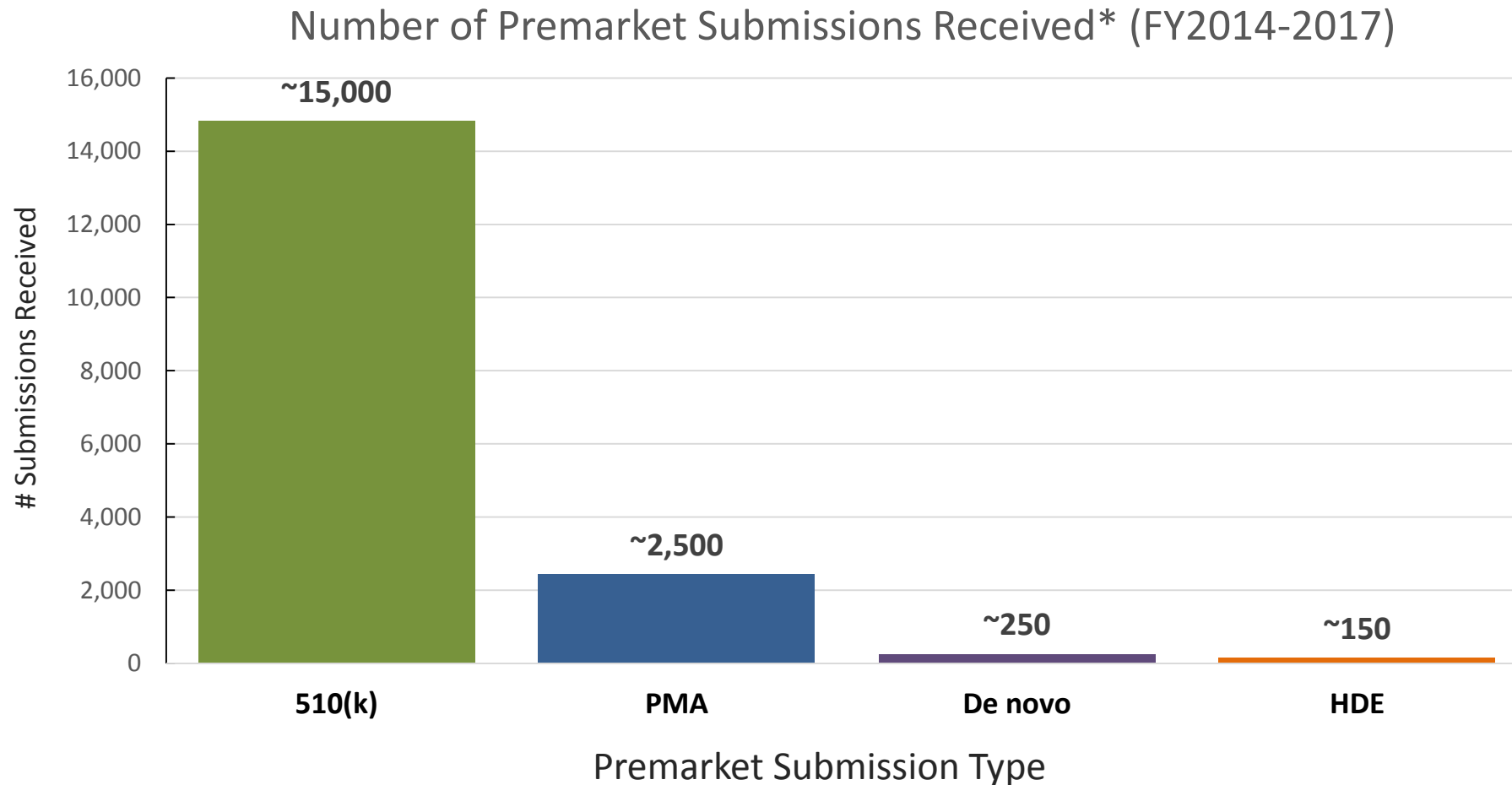


2017



FDA Reauthorization Act  
(MDUFA IV)

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



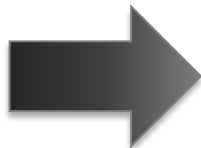
Source: MDUFA III Quarterly and Annual Reports (510(k), PMA, and De novo) and internal data (HDE)

\*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



2018 OIR Submissions Workshop Meeting Agenda		
Monday / April 23	9:00 a.m. – 5:00 p.m.	
8:00 – 9:00 a.m.		
9:00 – 9:45		
9:45 – 10:00		
10:00 – 10:30		
10:30 – 10:45		
10:45 – 11:00		
11:00 – 11:15		
11:15 – 11:30		
11:30 – 11:45		
11:45 – 12:00		
12:00 – 12:15		
12:15 – 12:30		
12:30 – 12:45		
12:45 – 1:00		
1:00 – 1:15		
1:15 – 1:30		
1:30 – 1:45		
1:45 – 2:00		
2:00 – 2:15		
2:15 – 2:30		
2:30 – 2:45		
2:45 – 3:00		
3:00 – 3:15		
3:15 – 3:45		
3:45 – 4:30		
4:30 – 5:00		
2018 Pre-Submissions Workshop Meeting Agenda		
Wednesday / April 25	8:15 a.m. – 10:30 a.m.	
8:15 – 8:30 a.m.		
8:30 – 8:45		
8:45 – 9:00		
9:00 – 9:15		
9:15 – 9:30		
9:30 – 9:45		
9:45 – 10:00		
10:00 – 10:15		
10:15 – 10:30		
2018 AMDM Annual Meeting Agenda		
Wednesday / April 25	8:15 a.m. – 10:30 a.m.	
8:15 – 8:30 a.m.		
8:30 – 8:45		
8:45 – 9:00		
9:00 – 9:15		
9:15 – 9:30		
9:30 – 9:45		
9:45 – 10:00		
10:00 – 10:15		
10:15 – 10:30		
2018 Educational Workshop & Meeting		
10:30 – 10:45	Break	
10:45 – 11:15	Replacement Reagent and Instrument Family Policy Guidance Ava Darnovsky, CDRI, FDA - <a href="mailto:ava.darnovsky@fda.hhs.gov">ava.darnovsky@fda.hhs.gov</a>	
11:15 – 11:35	De Novo Process Experience Karin Hughes, Vice President Clinical & Regulatory Strategic, Artile Medical, Inc. - <a href="mailto:khughes@artilemedical.com">khughes@artilemedical.com</a>	
11:35 – 12:00	Companion Diagnostics Experience Lesley Farrington, Director of Global Regulatory Affairs Diagnostics, Janssen - <a href="mailto:lfarrington@janssen.com">lfarrington@janssen.com</a>	
12:00 – 1:00	Lunch	White Oak A
1:00 – 1:30	Program for FDA-CMS Parallel Review: What You Need to Know Rochelle Fink, CDRI, FDA - <a href="mailto:Rochelle.Fink@fda.hhs.gov">Rochelle.Fink@fda.hhs.gov</a>	
1:45 – 2:25	Reimbursement: Understanding Key Concepts to Maximize Business Success Tom Hughes, Sr. Principal Advisor Health Economics & Reimbursement, ACB - <a href="mailto:thughes@acbi.com">thughes@acbi.com</a>	
2:25 – 3:00	IVDR Update Juli Smith, VP, In Vitro Diagnostics & Quality, Precision for Medicine - <a href="mailto:juli.smith@precisionformedicine.com">juli.smith@precisionformedicine.com</a>	
3:00 – 3:15	Review & Wrap Up Ann Quirey, Karen Richards, Carol Ryerson, Meeting Co-Chairs	

# Understanding 510(k) begins with three key concepts

1. Regulatory Context

A vertical flowchart with three colored rectangular boxes. The top box is blue and contains the text "1. Regulatory Context". A light blue arrow points down from the bottom right of this box to the top right of the middle box. The middle box is purple and contains the text "2. Essential Processes". Another light blue arrow points down from the bottom right of the middle box to the top right of the bottom box. The bottom box is teal and contains the text "3. Resources".

2. Essential Processes

3. Resources

# Understanding 510(k) begins with three key concepts

1. Regulatory Context

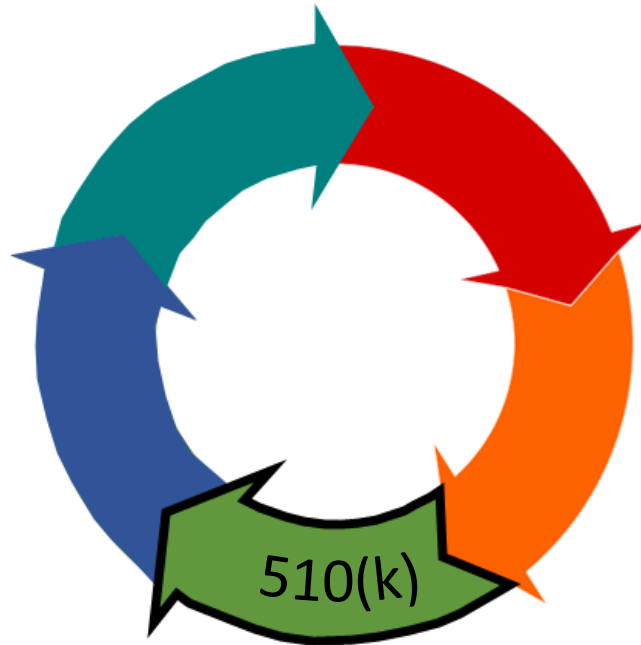
A vertical flowchart with three rectangular boxes. The top box is dark blue with white text. The middle and bottom boxes are light gray with white text. A large, light gray arrow points from the bottom of the first box to the top of the second box. Another large, light gray arrow points from the bottom of the second box to the top of the third box.

2. Essential Processes

3. Resources

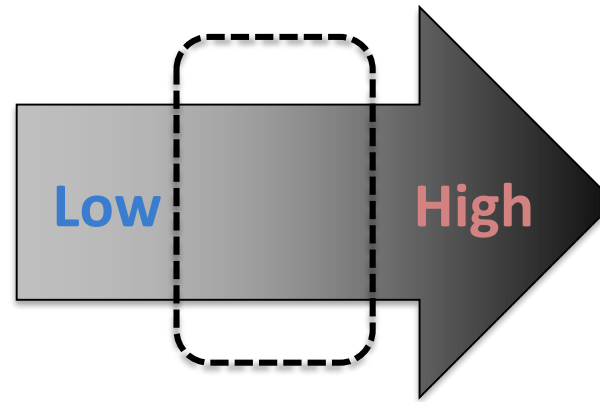
# 510(k)s are one part of a large regulatory ecosystem

## Device Life Cycle



Type of Premarket submission

## Risk



Moderate Risk devices

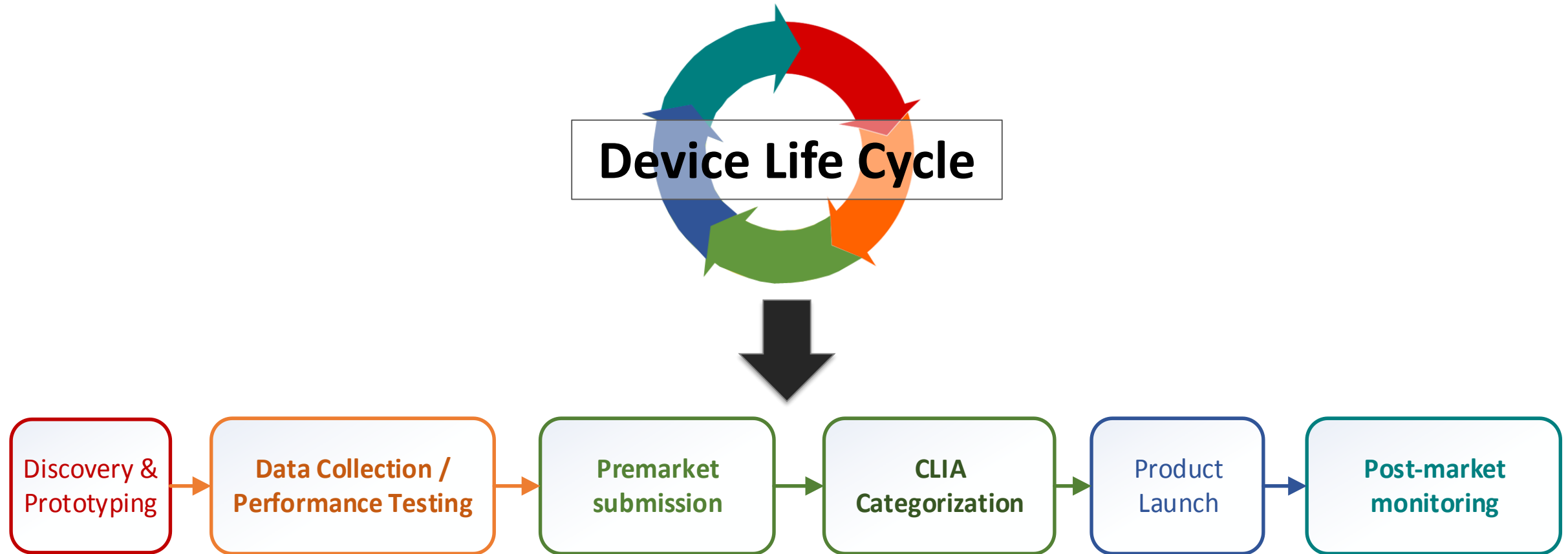
## Review Standard



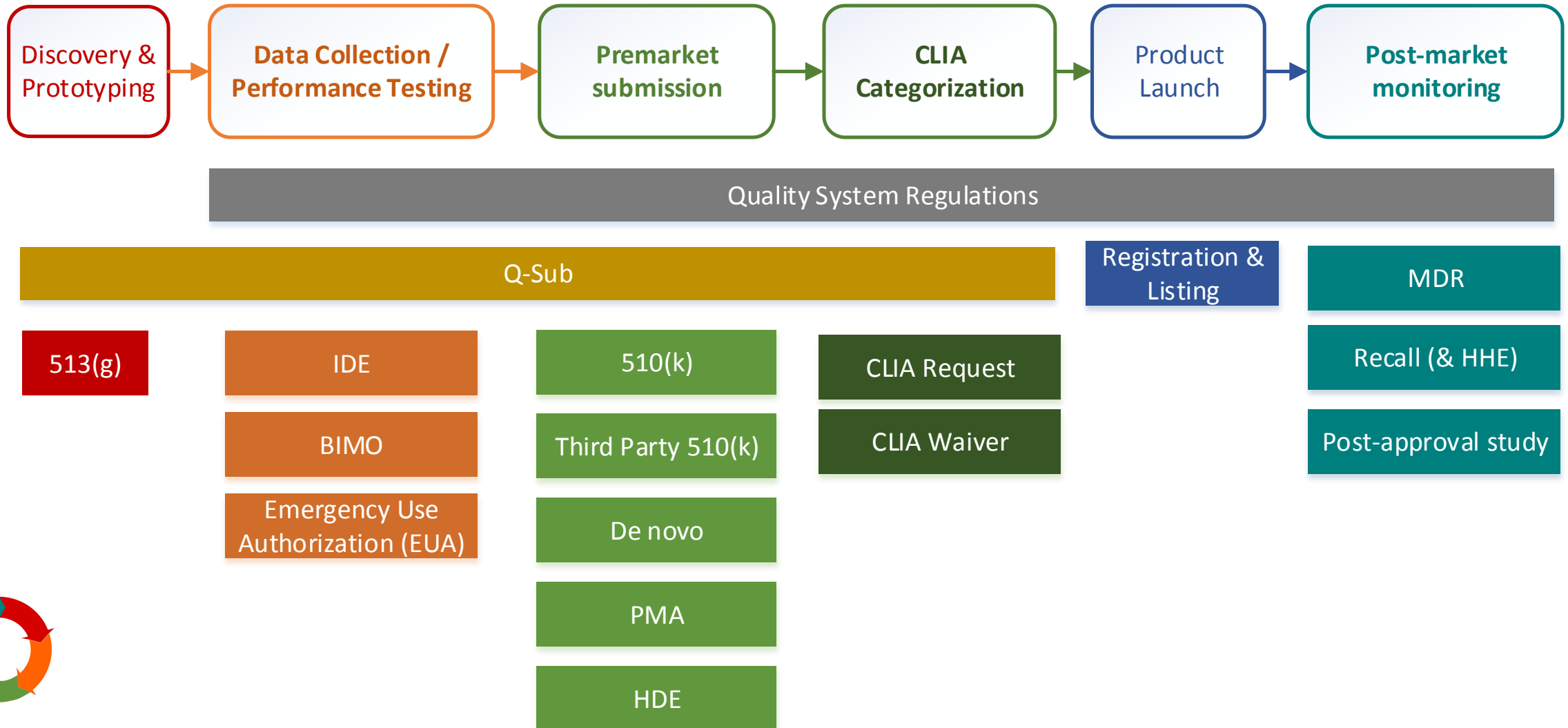
Compared to a predicate



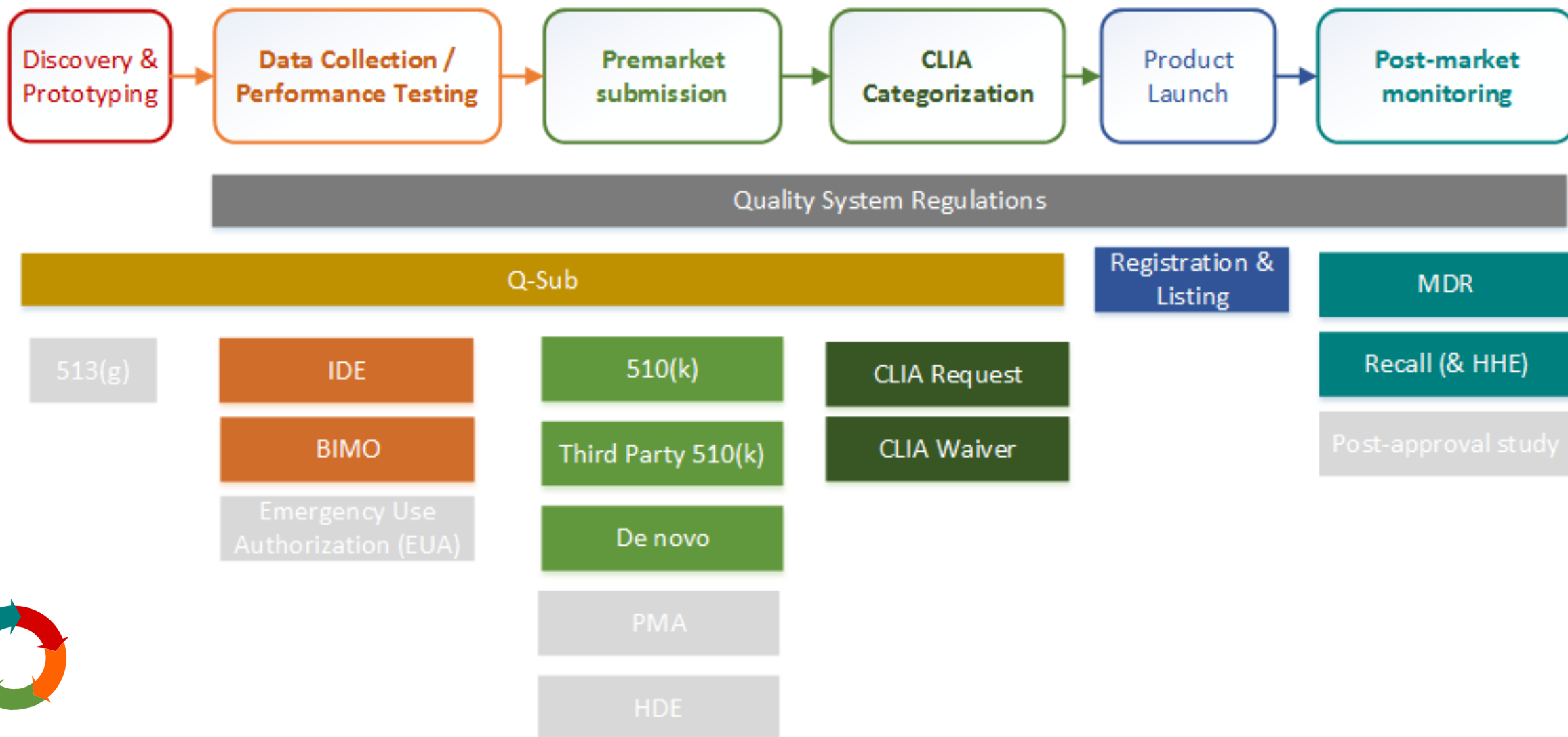
# A device goes through several steps throughout its life cycle



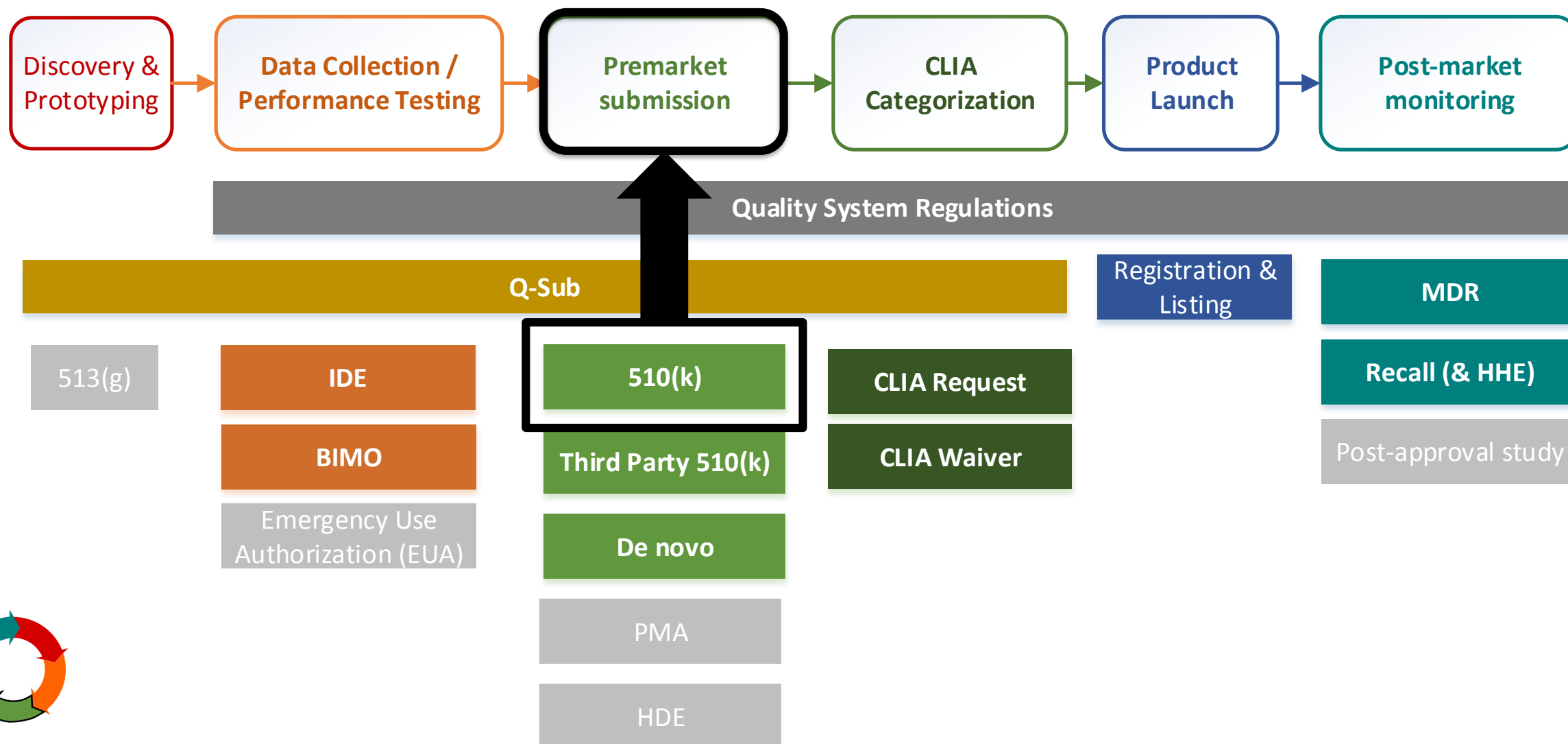
# There are many regulatory activities throughout a device's life cycle



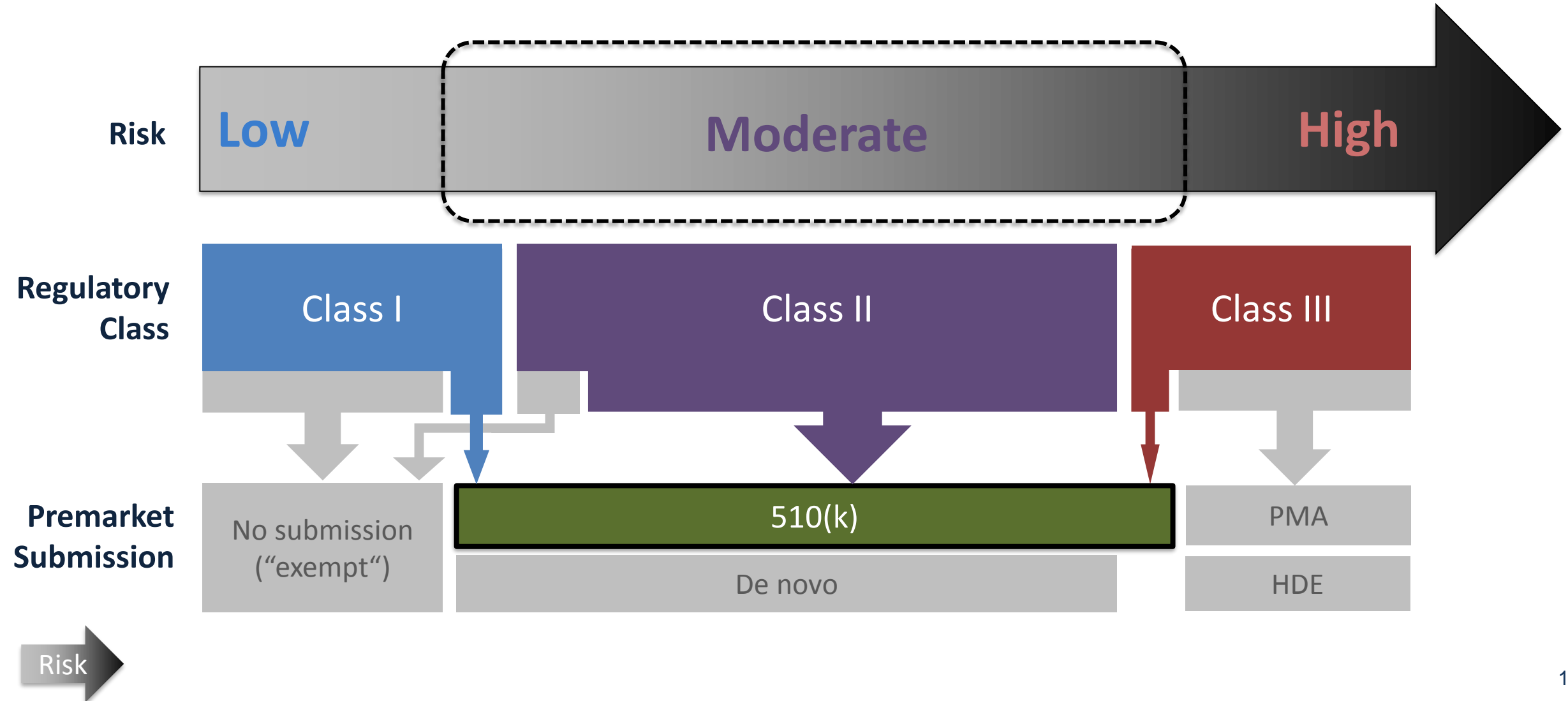
# We will cover most regulatory activities in this workshop



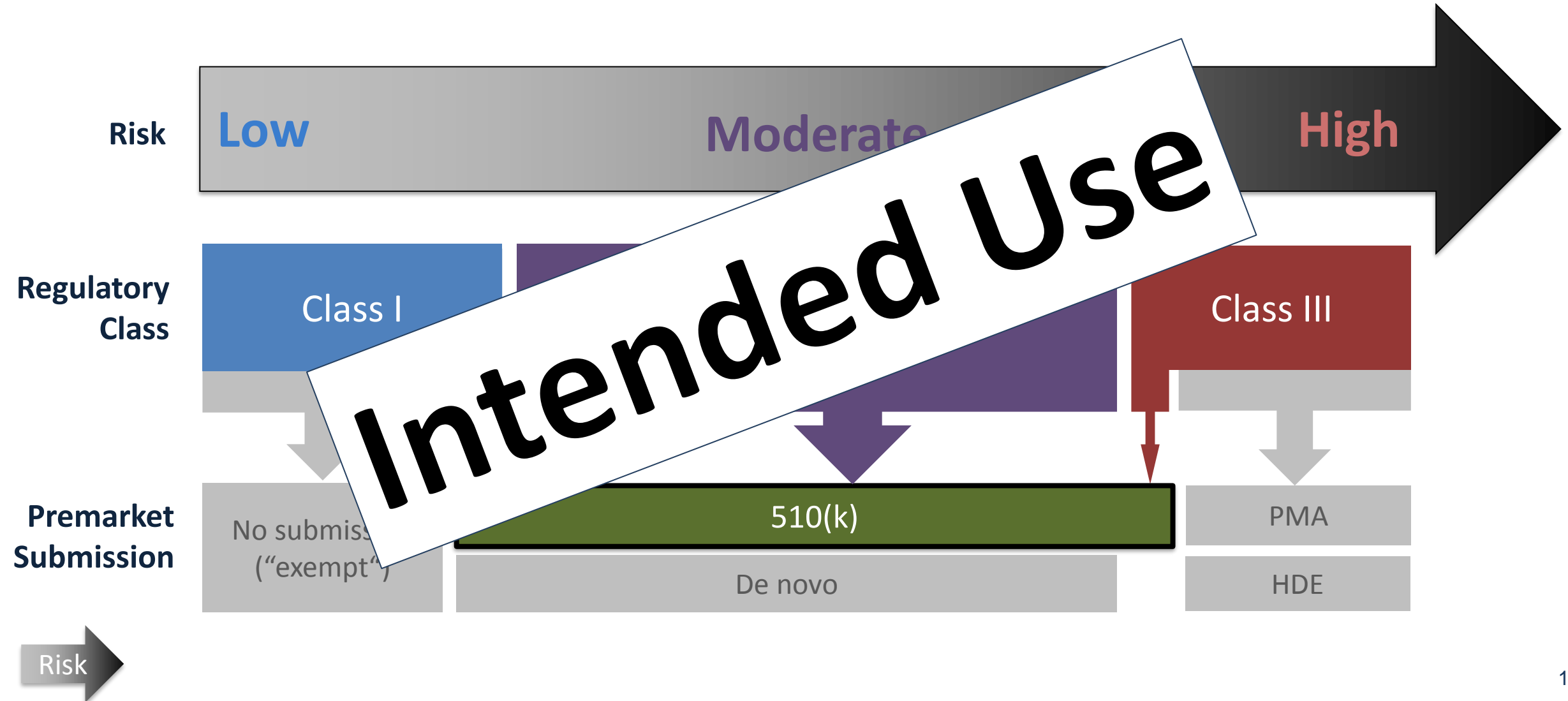
# 510(k) is one of several types of premarket submissions



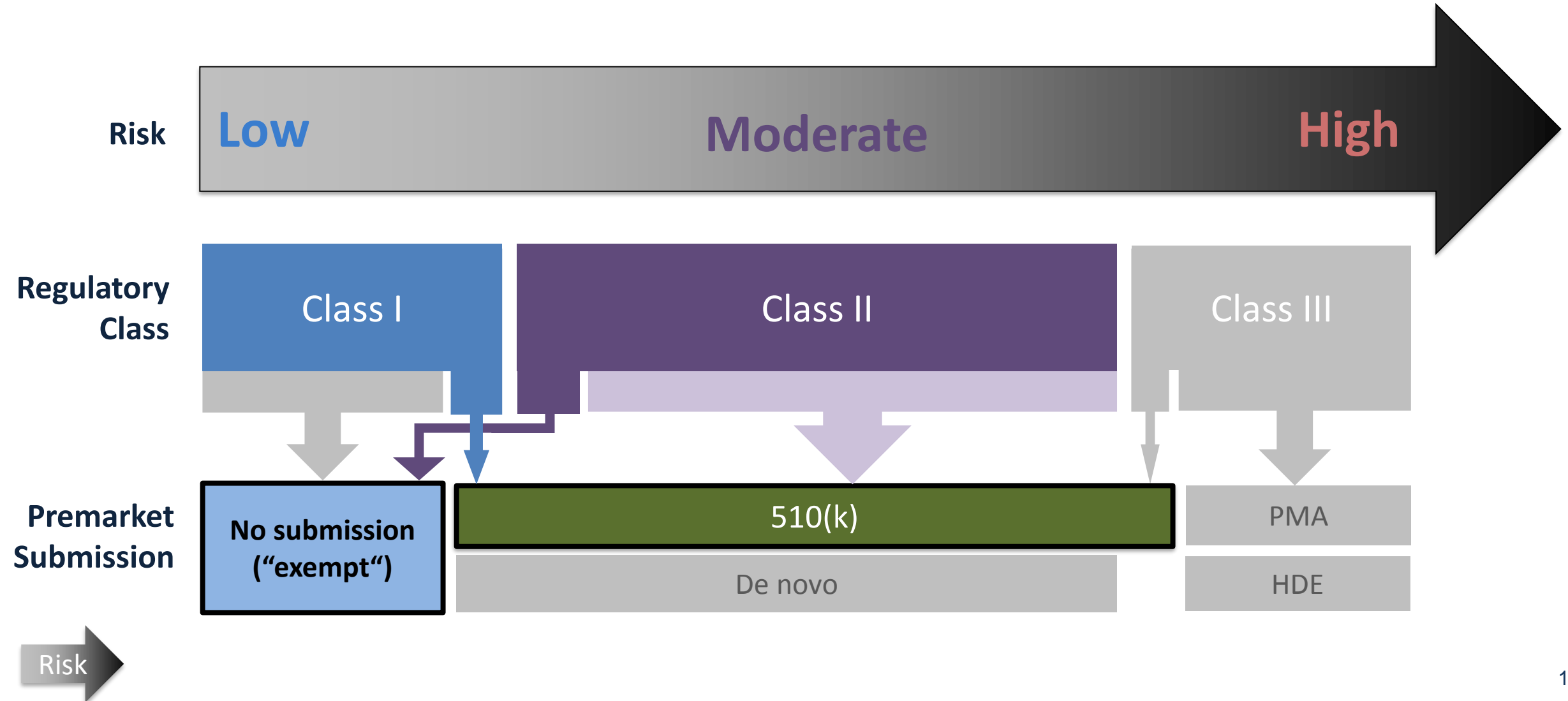
# 510(k)s are required for most moderate risk and some low & high risk devices



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”

## 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 general purpose device is limited to the following uses:

- 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]

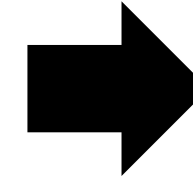
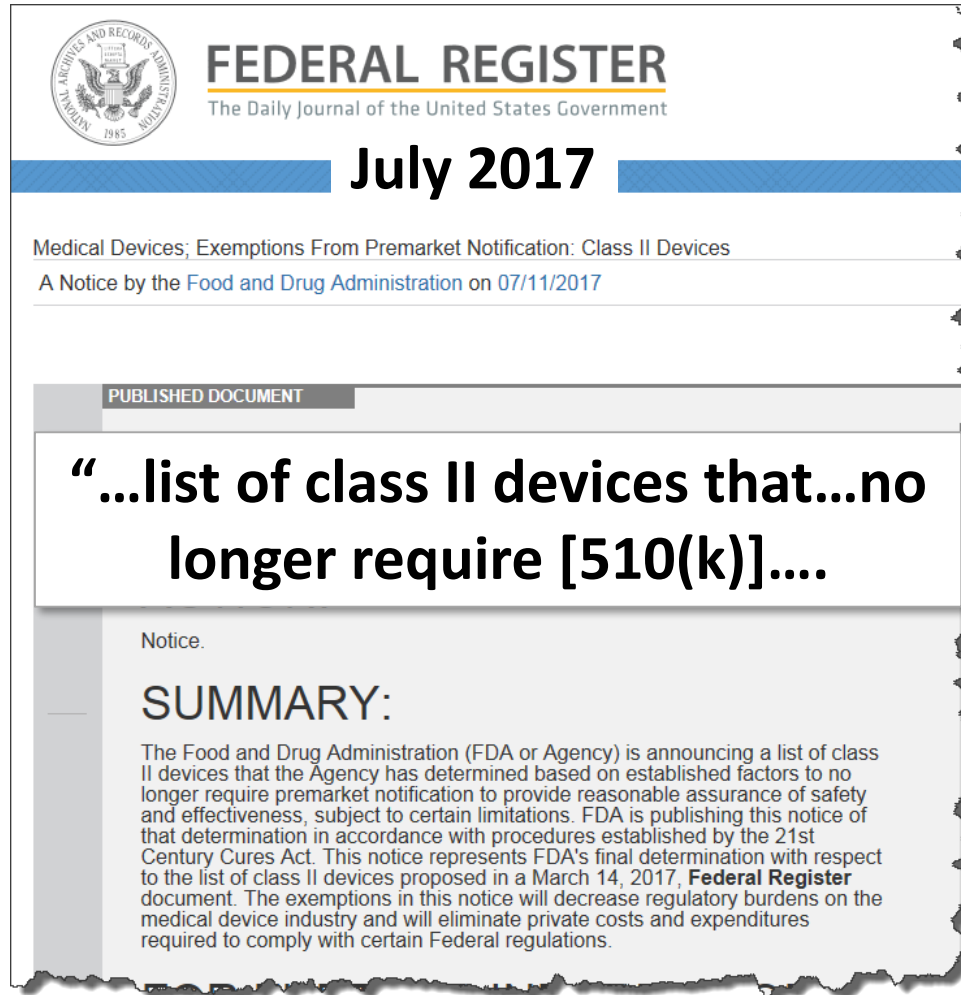
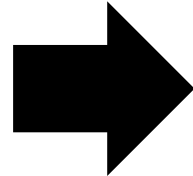
Class I

510(k)



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

Class II



No Submission  
("exempt")

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

## Review Standard



510(k)

De novo

PMA

HDE

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

## Review Standard



510(k)

=

**Comparative**

("substantially equivalent" to a "predicate")

De novo

PMA

HDE

**= Stand-alone**

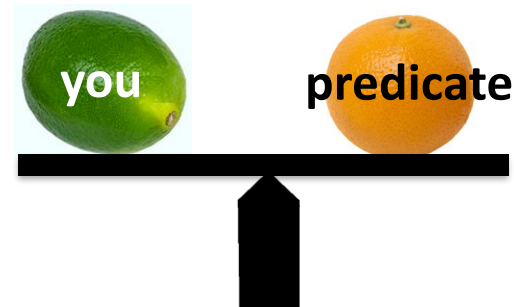
# In 510(k), a device is compared to a predicate in two stages

## Review Standard

**Stage 1:** Is 510(k) appropriate?



**Stage 2:** Does the data establish equivalence?



Safety &  
Effectiveness

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

## Review Standard

Stage 1: Is 510(k) predicate?

predicate

**Intended Use**

Stage 2: Does the data establish equivalence?

you

predicate

Effectiveness

# 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.  **you** 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

Marketed in U.S.  
Does not require PMA

# One Predicate Device

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



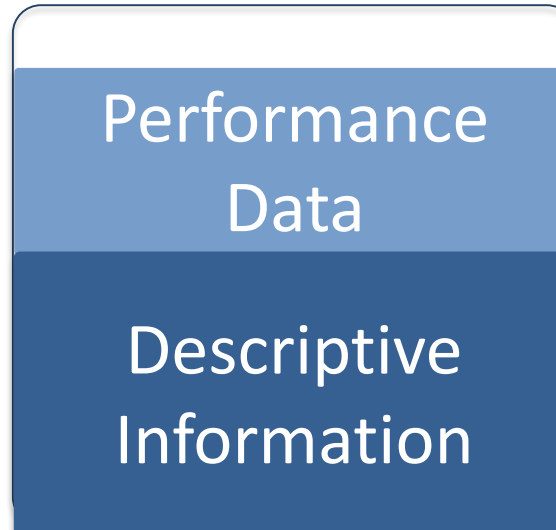
# Stage 2: To be found SE, a device should be as safe and effective as the predicate

**Primary predicate**  
(+ Reference devices)



=

**Your device**



OR



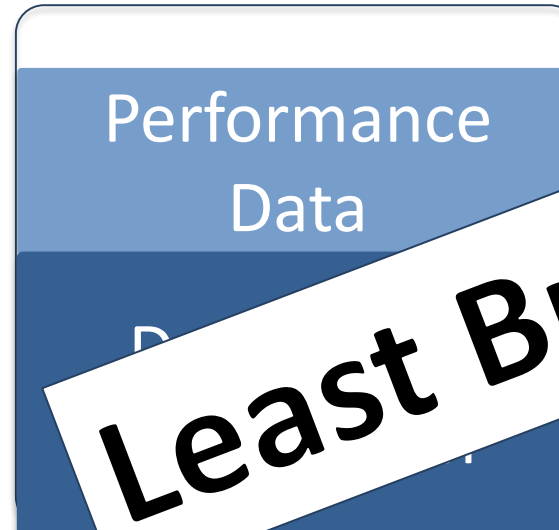
# Stage 2: To be found SE, a device should be as safe and effective as the predicate

**Primary predicate**  
(+ Reference devices)



=

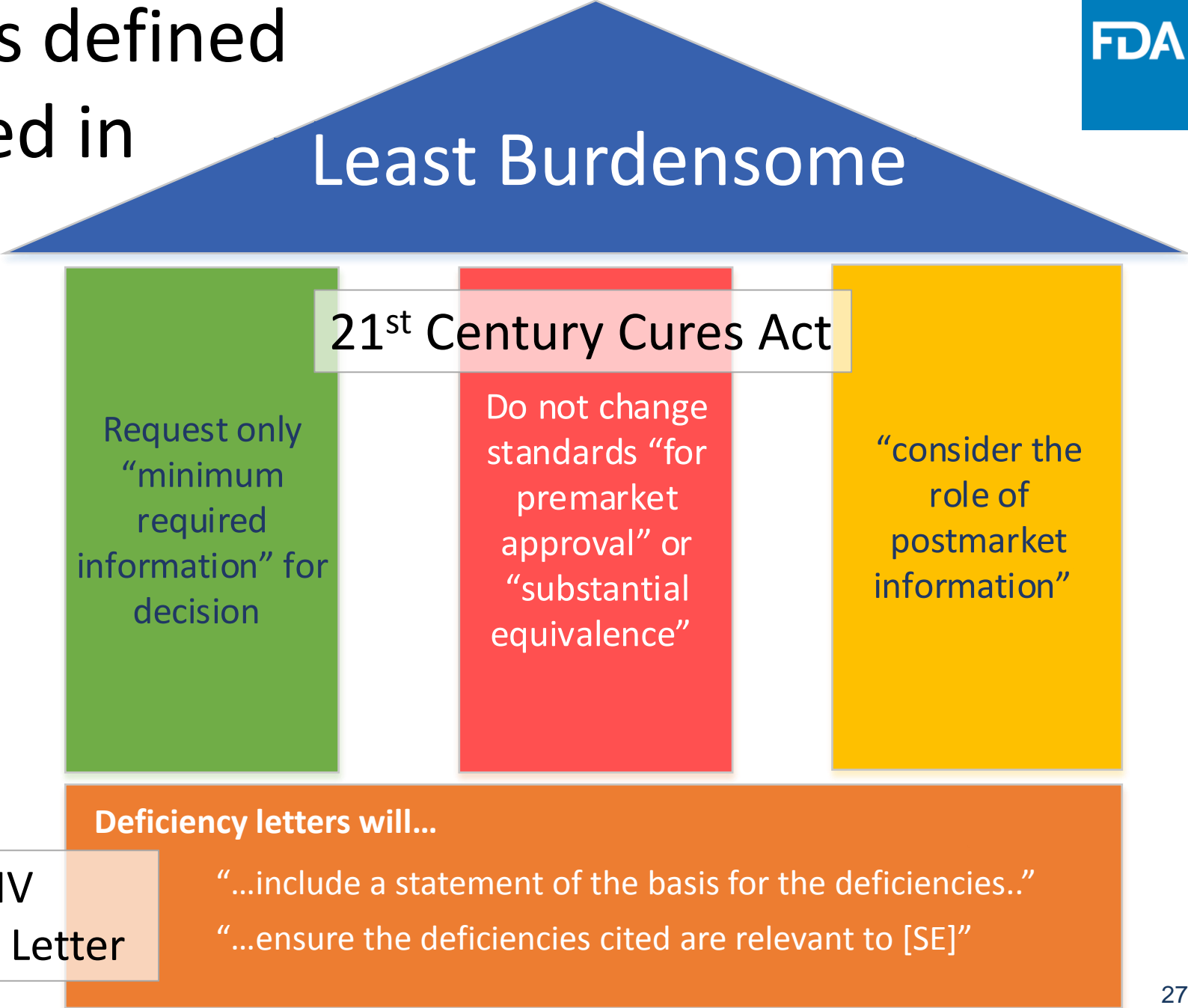
**Your device**



**Least Burdensome**



# Least Burdensome is defined by law and supported in MDUFA IV



# Understanding 510(k) begins with three key concepts

1. Regulatory Context

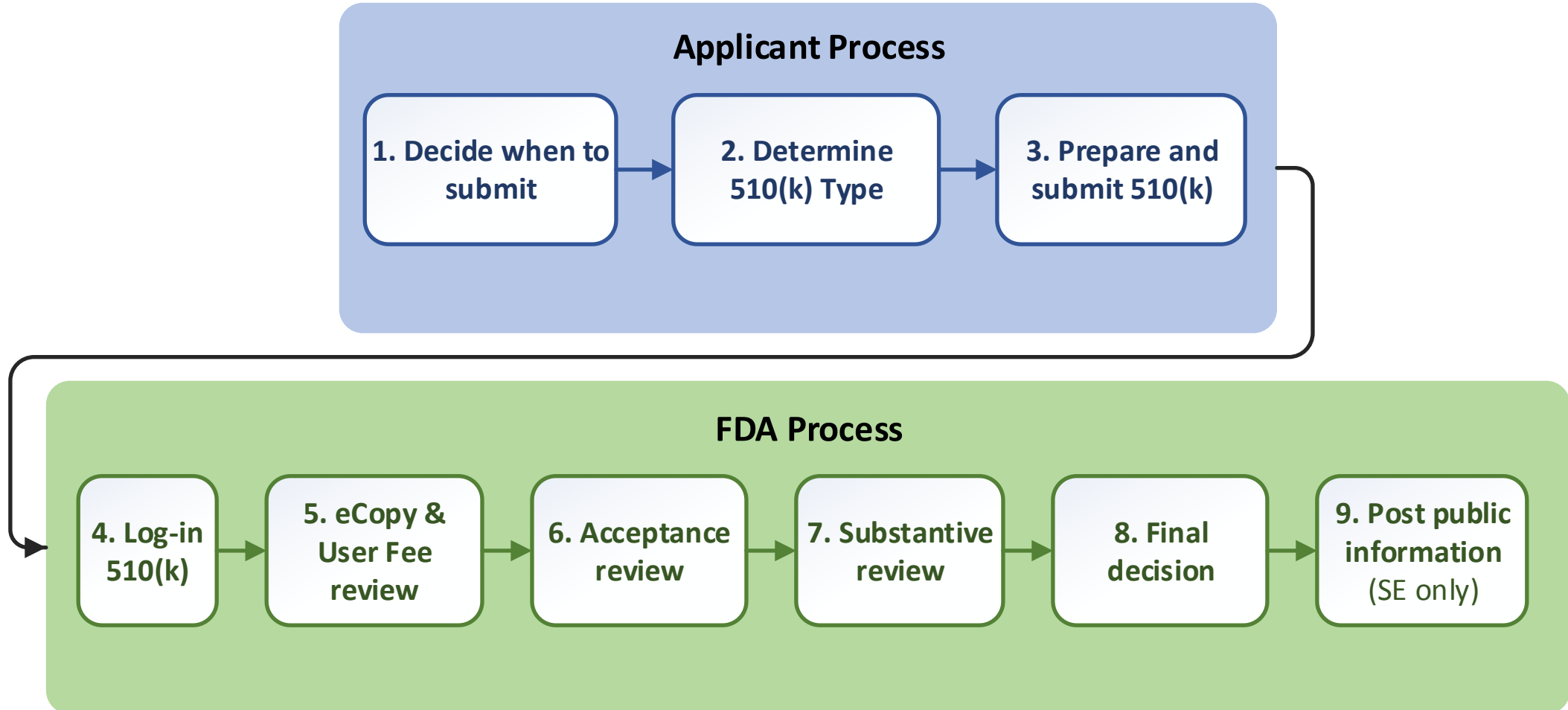
A light gray downward-pointing arrow connects the first box to the second box.

2. Essential Processes

A light gray downward-pointing arrow connects the second box to the third box.

3. Resources

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



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

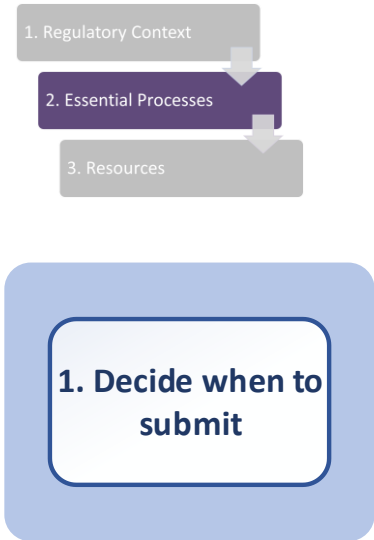
## Applicant Process

1. Decide when to submit

2. Determine 510(k) Type

3. Prepare and submit 510(k)

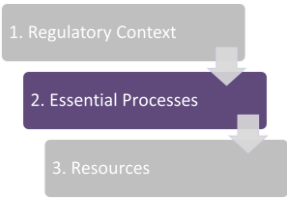
# A new 510(k) is required for new and modified devices



A 510(k) is required when:

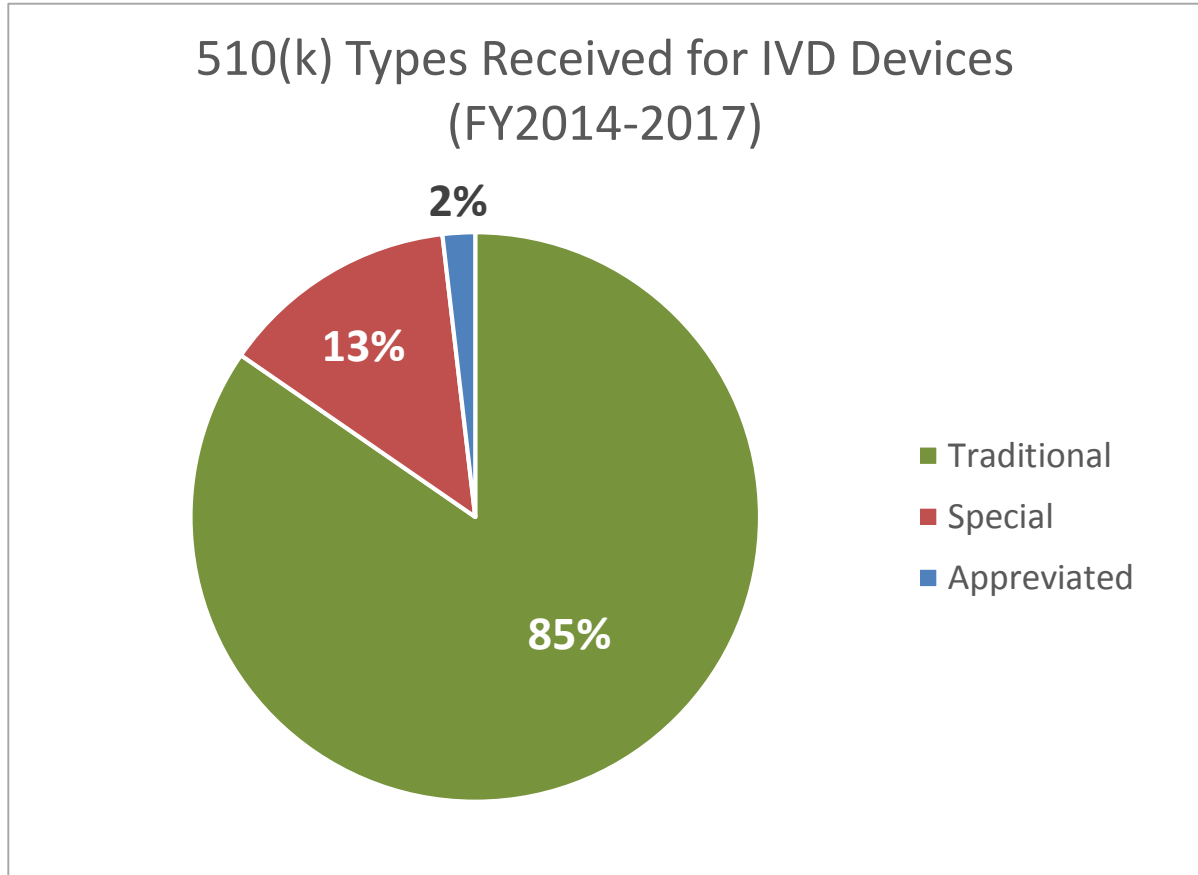
- Introducing device to U.S. market for the first time
- New or different intended use
- Device modification that “could significantly affect safety or effectiveness”

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



## 2. Determine 510(k) Type

<b>Traditional</b>	<ul style="list-style-type: none"> <li>• Most common</li> <li>• Review all relevant performance data</li> </ul>
<b>Special</b>	<ul style="list-style-type: none"> <li>• Certain changes</li> <li>• Rely on summary of results from design control process</li> </ul>
<b>Abbreviated</b>	<ul style="list-style-type: none"> <li>• Rely on conformance to guidance documents, special controls, and/or recognized standards</li> </ul>





# 510(k)s should be complete and high quality

## 3. Prepare and submit 510(k)

### Complete

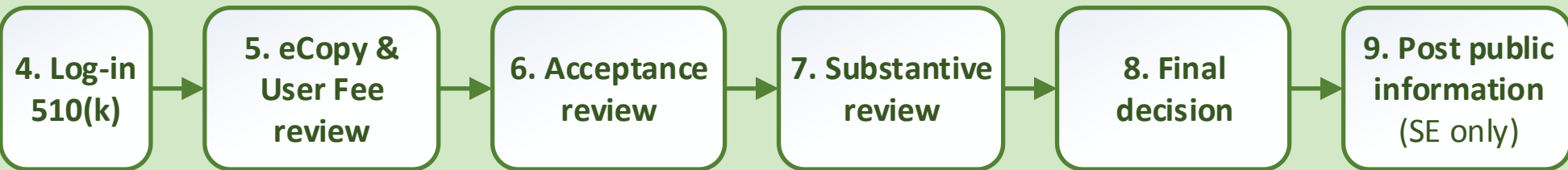
- ✓ Contact info
- ✓ Primary predicate
- ✓ RTA checklist elements
- ✓ eCopy
- ✓ User Fee

### Quality

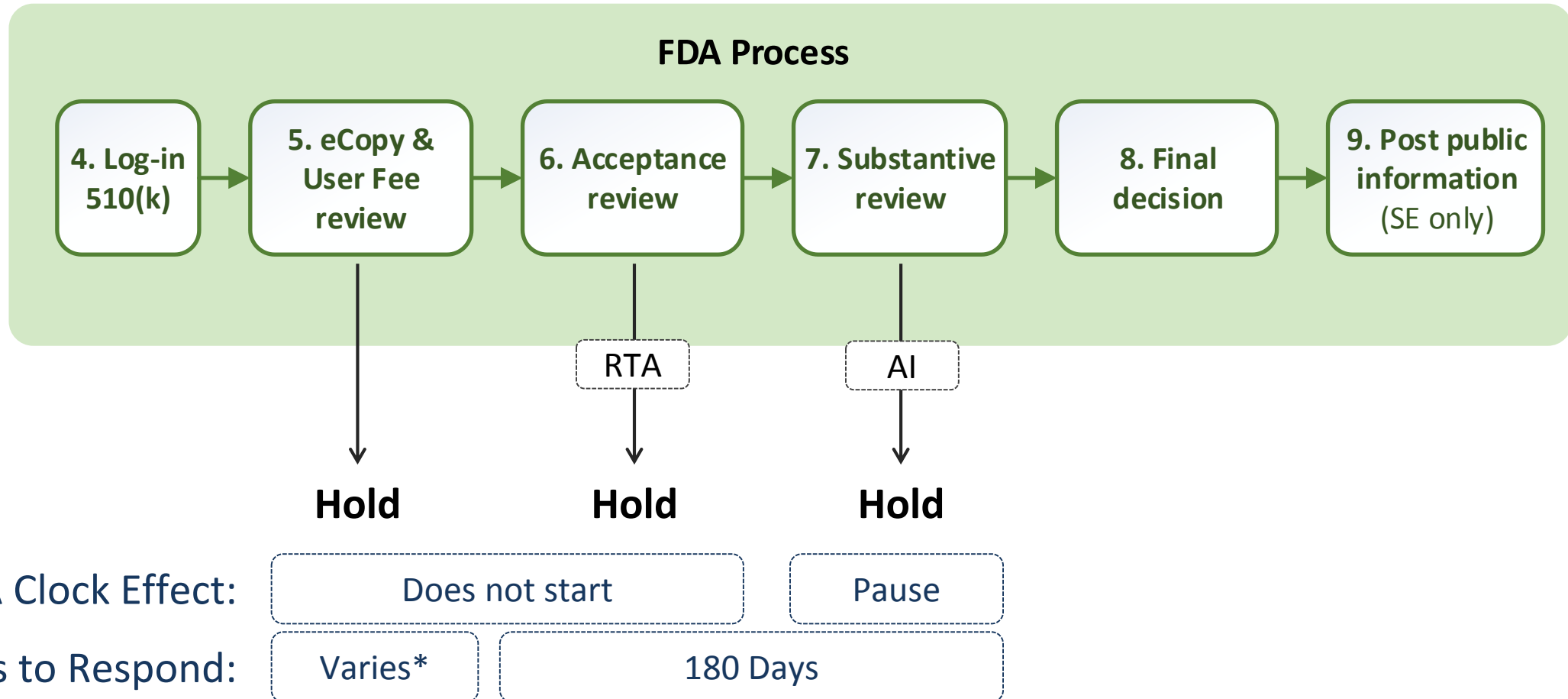
- Organized
- Consistent
- Purposeful
- Tell the story of equivalence

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

## FDA Process

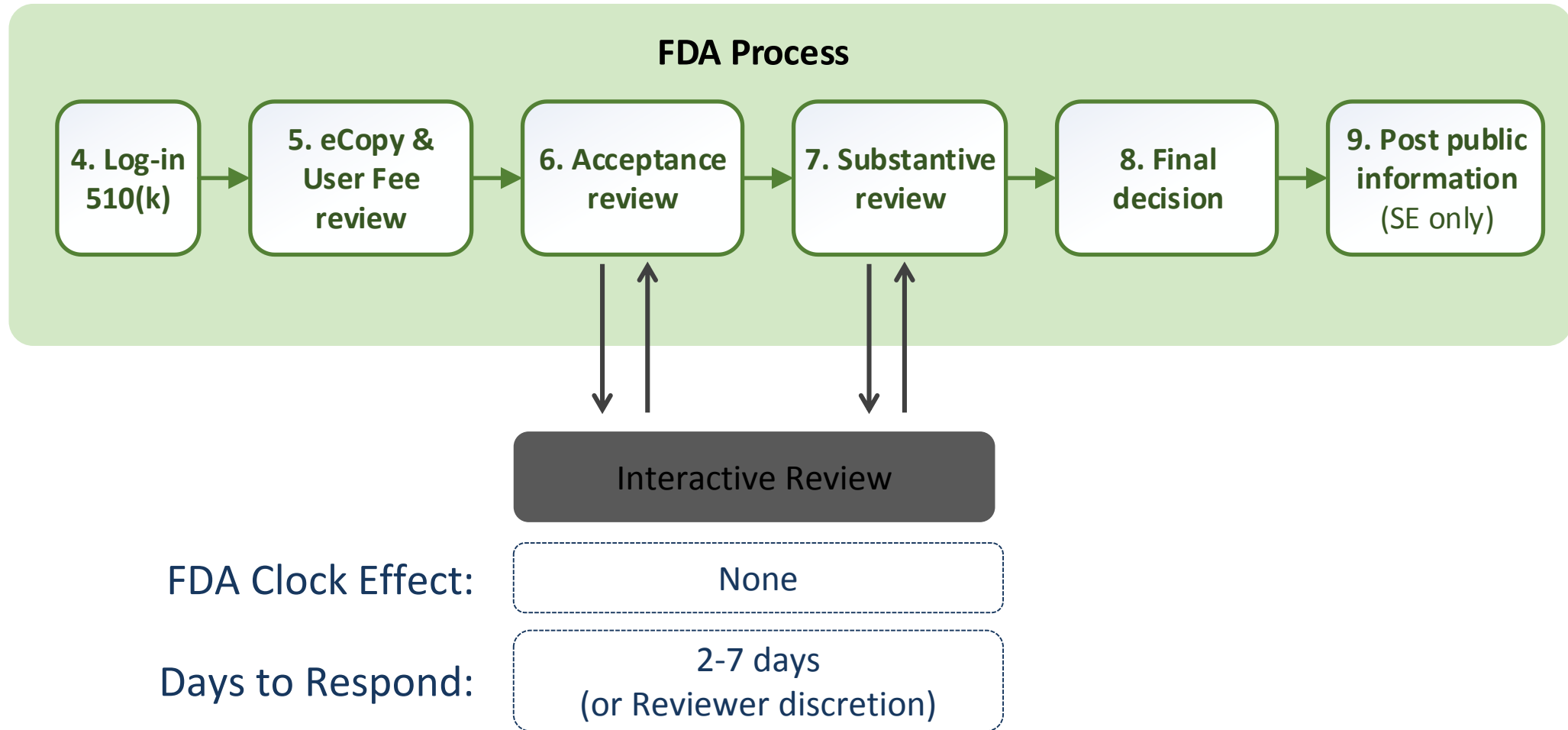


# FDA's 510(k) process is subject to "Hold"

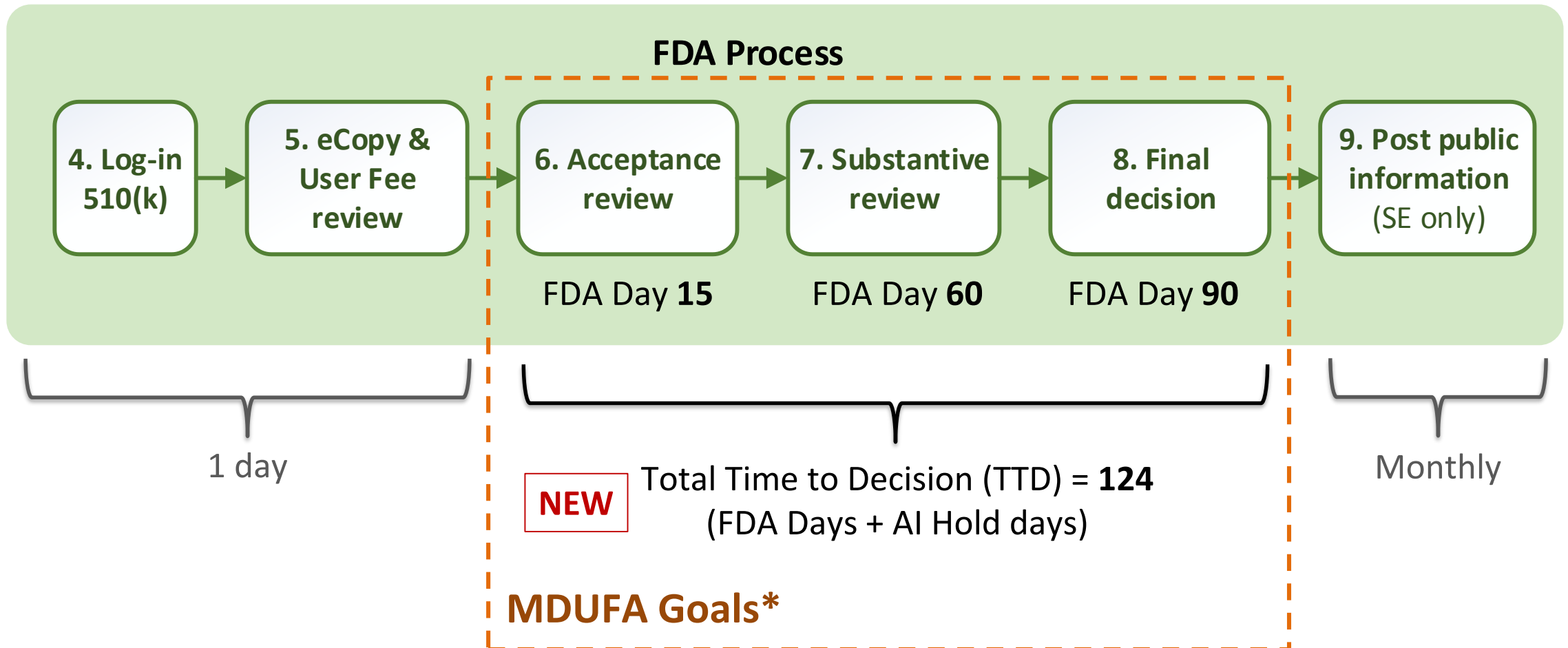


\*Depends on whether Original or response to RTA or AI hold

# FDA's 510(k) process is interactive

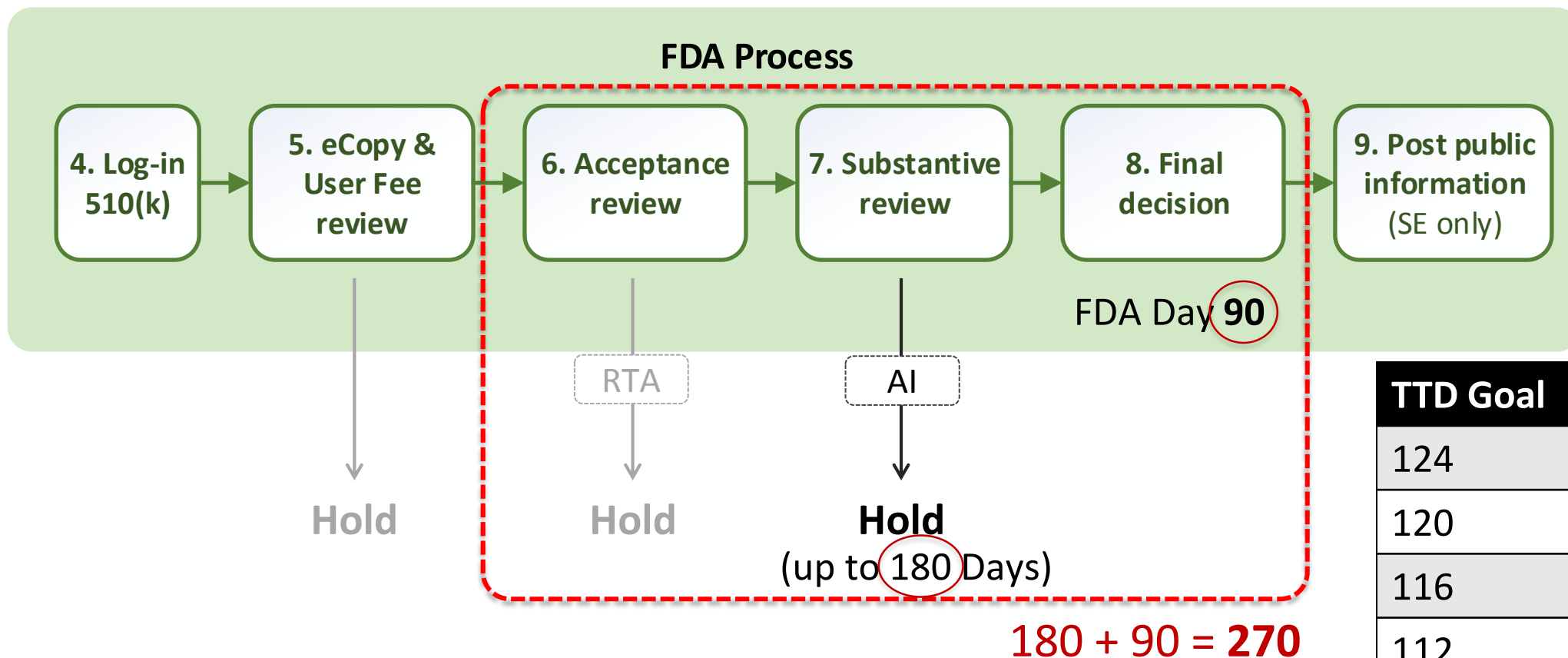


# FDA's 510(k) process is subject to MDUFA and other goals



*\*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

1. Regulatory Context
2. Essential Processes
3. Resources

## 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

If you (809), (800) <http://www.fda.gov> the re 807.9 CFR <http://www.fda.gov> of Su

**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Public Health Service  
Food and Drug Administration  
10903 New Hampshire Avenue  
Department Control Center - White Oak  
Silver Spring, MD 20993-0002

October 19, 2017

**ABOTT LABORATORIES**  
NOAH LERNER, PH.D.  
REGULATORY AFFAIRS DIRECTOR  
DEPT. 9A-3, BLDG C-001-1

## SE Letter

Regulatory Class: II  
Product Code: CFR, IJE  
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**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.

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

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

VII. Summary of Nonclinical Performance

D. Principles of the Procedure

R. Alinity c Multiconstituent Calibrator Kit

IV. Description of Device

Device Name: 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

## 510(k) Summary\*

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

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

# After an SE decision, we will publicly post four documents

1. Regulatory Context
2. Essential Processes
3. Resources

## 9. Post public information (SE only)

### 510(k) Premarket Notification

FDA Home Medical Devices Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification  
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search

Back To Search Results

Device Classification Name [Hexokinase\\_Glucose](#)  
510(k) Number K170316  
Device Name ALINITY C GLUCOSE REAGENT KIT, ALINITY C SYSTEM  
Applicant Abbott Laboratories  
Dept. 09AA, Bldg CP1-3, 100 Abbott Park Road  
Abbott Park, IL 60064  
Applicant Contact Noah Lerner  
Correspondent Abbott Laboratories  
Dept. 09AA, Bldg CP1-3, 100 Abbott Park Road  
Abbott Park, IL 60064  
Correspondent Contact Noah Lerner  
Regulation Number [862.1345](#)  
Classification Product Code [CFR](#)  
Subsequent Product Code [JJE](#)  
Date Received 02/01/2017  
Decision Date 10/19/2017  
Decision Substantially Equivalent (SESE)  
Regulation Medical Specialty Clinical Chemistry  
510(k) Review Panel Clinical Chemistry  
Summary [Summary](#)  
FDA Review [Decision Summary](#)  
Type Traditional  
Reviewed By Third Party No  
Combination Product No

## SE Letter

## IFU Statement

## 510(k) Summary

&

## IVD Decision Summary

F. Proprietary and Established Names:

Alinity c Glucose Reagent Kit  
Alinity c System

G. Regulatory Information:

1. Regulation section:

Device	Product Code	Classification	Regulation	Panel
Alinity c Glucose Reagent Kit	CFR	Class II	CFR 862.1345 Glucose test system	Clinical Chemistry (75)
Alinity c System	JJE	Class I	CFR 862.2160 Discrete photometric chemistry analyzer for clinical use	



# Understanding 510(k) begins with three key concepts

1. Regulatory Context

A vertical flowchart illustrating the three key concepts for understanding 510(k). It consists of three rectangular boxes arranged vertically. The first box, labeled "1. Regulatory Context", is light gray. A light gray arrow points down from its bottom center to the second box. The second box, labeled "2. Essential Processes", is also light gray. Another light gray arrow points down from its bottom center to the third box. The third box, labeled "3. Resources", is a darker teal color. The boxes are slightly offset to the right as they descend.

2. Essential Processes

3. Resources

- 1. Regulatory Context
- 2. Essential Processes
- 3. Resources



# Resources are available to help



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

Guidance for Industry

Drug

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.

Center for Devices and Radiological Health

C/DRH

Center for Biologics Evaluation and Research

C/BER

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  
Product Code: 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
<a href="#">Alinity C Glucose Reagent Kit, Alinity C</a>	Abbott Laboratories	<a href="#">K170318</a>	10/19/2017
<a href="#">Ise Reagent, Glucose, Crp Latex, Dxc 700</a>	Beckman Coulter Inc.	<a href="#">K161837</a>	12/16/2016
<a href="#">Elitech Clinical Systems Glucose Hk Sl</a>	Elitechgroup	<a href="#">K153644</a>	09/07/2016
<a href="#">Diatron Pictus 700 Clinical Chemistry An</a>	Diatron Us, Inc.	<a href="#">K151487</a>	01/14/2016
<a href="#">Carolina Liquid Chemistries Clc 6410 Ch</a>	Carolina Liquid Chemistries Corp.	<a href="#">K133519</a>	05/16/2014

Predicates

<a href="#">Hitachi Clinical Analyzer S Test Reagent</a>	Hitachi Chemical Diagnostics, Inc.	<a href="#">K120369</a>	05/10/2012
<a href="#">Biolis 12i</a>	Tokyo Boeki Medsys Inc.	<a href="#">K110520</a>	03/23/2012
<a href="#">Bs-400 Chemistry Analyzer, Clc 720 Chemi</a>	Shenzhen Mindray Bio-Medical Electronics	<a href="#">K112377</a>	03/23/2012
<a href="#">Liasys 450</a>	Ams	<a href="#">K113131</a>	03/08/2012
<a href="#">Au5800(R) Chemistry Analyzer</a>	Beckman Coulter, Inc.	<a href="#">K112412</a>	12/23/2011
<a href="#">Prestige 24i, Biolis 24i, Moc 240</a>	Tokyo Boeki Medsys Inc.	<a href="#">K103531</a>	12/01/2011
<a href="#">Dimension Clinical Chemistry System</a>	Siemens Healthcare Diagnostics	<a href="#">K112999</a>	11/22/2011
<a href="#">Pentra C200, Ise Module And Abx Pentra G</a>	Horiba Abx Sas	<a href="#">K103788</a>	11/08/2011
<a href="#">Indiko</a>	Thermo Fisher Scientific Oy	<a href="#">K110035</a>	06/28/2011
<a href="#">Advia Chemistry Glucose Hexokinase 3 (G)</a>	Siemens Healthcare Diagnostics	<a href="#">K101854</a>	03/07/2011
<a href="#">Cobas 8000 Modular Series Analyzer</a>	Roche Diagnostics Corp.	<a href="#">K100853</a>	09/09/2010
<a href="#">Easysa Glu-T Reagent, Easysa Glu-H Reage</a>	Medica Corp.	<a href="#">K100187</a>	05/05/2010
<a href="#">Cobas Integra Glucose Hk Gen 3 Assay</a>	Roche Diagnostics	<a href="#">K092603</a>	12/04/2009
<a href="#">Poly-Chem 90 Glucose</a>	Polymedco, Inc.	<a href="#">K090703</a>	10/20/2009
<a href="#">Easysa Glu-H Reagent, Model 10200</a>	Medica Corp.	<a href="#">K092506</a>	09/16/2009

1 2 3 4 5 6 7 >



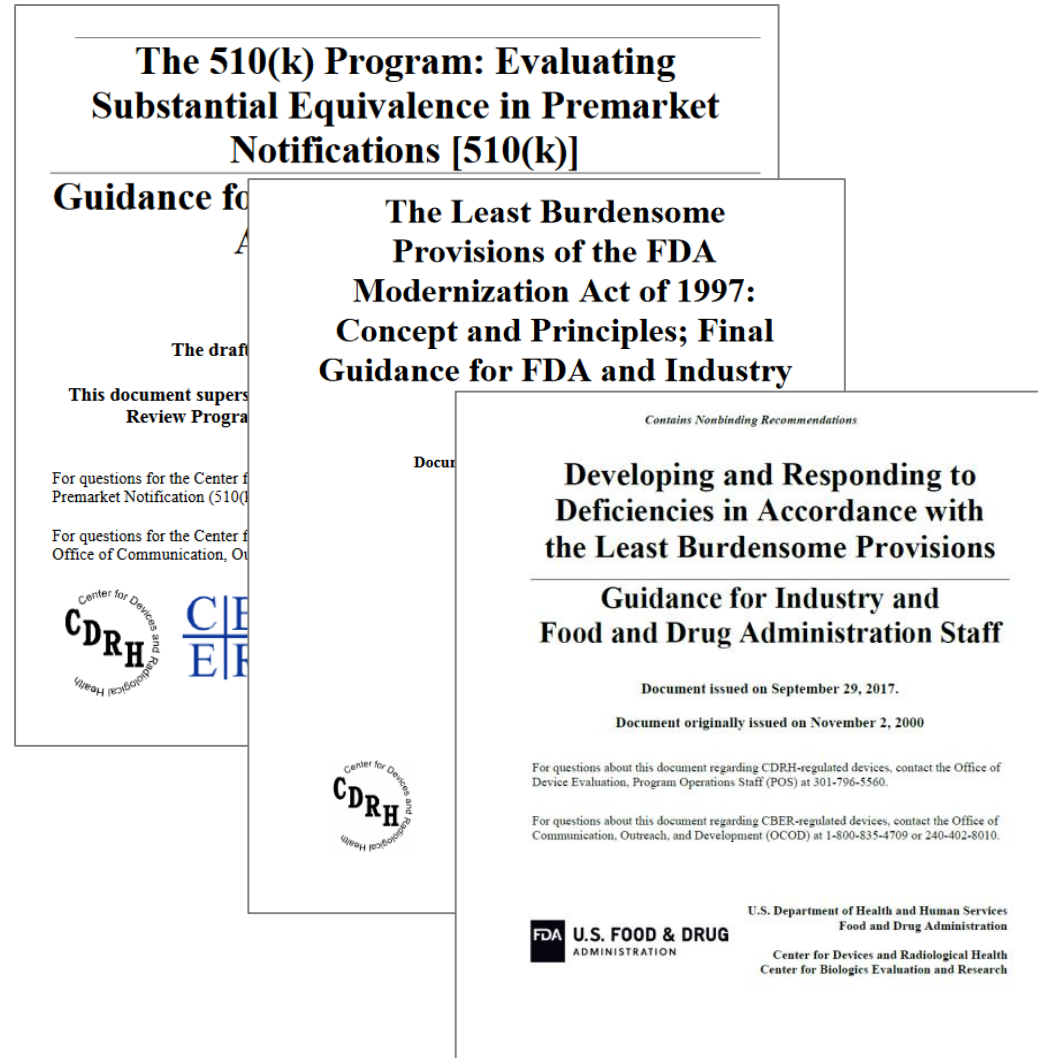
People

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

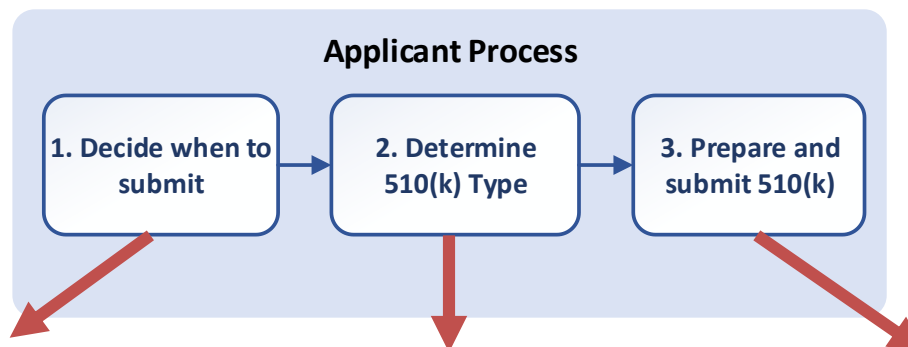
## Review Standard



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](mailto: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.



**FDA 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

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Document  
The inform  
0910-012  
required t  
For quest  
document  
biocompa



### 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.

**FDA U.S. FOOD & DRUG ADMINISTRATION**

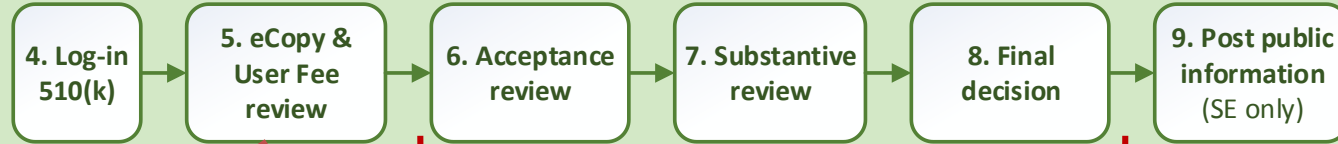
U.S. Department of Health and Human Services  
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

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

## FDA Process



### 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](mailto: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  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

### 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](mailto: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. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

- 1. Regulatory Context
- 2. Essential Processes
- 3. Resources



# Reviewing predicate 510(k)s and Decision Summaries can help

### 510(k) Premarket Notification

FDA Home Medical Devices Databases

Search Database

510K Number

Type

Product Code

CFR

Center

Combination Products

Cleared/Approved Products

Redacted 510(k)

Applicant Name

Device Name

Panel

Decision

Decision Date

Sort by

Quick Search

1 to 10 of 175 Results

Product Code: cfr Decision Date To: 04/11/2018

Results per Page 10

New Search

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

Device Name	Applicant	510(K) Number	Decision Date
<a href="#">Alinity C Glucose Reagent Kit, Alinity C</a>	Abbott Laboratories	<a href="#">K170316</a>	10/19/2017
<a href="#">Ise Reagent, Glucose, Crp Latex, Dxc 700</a>	Beckman Coulter Inc.	<a href="#">K161837</a>	12/16/2016
<a href="#">Elitech Clinical Systems Glucose Hk Sl</a>	Elitechgroup	<a href="#">K153644</a>	09/07/2016
<a href="#">Diatron Pictus 700 Clinical Chemistry An</a>	Diatron Us, Inc.	<a href="#">K151487</a>	01/14/2016
<a href="#">Carolina Liquid Chemistries Clc 6410 Ch</a>	Carolina Liquid Chemistries Corp.	<a href="#">K133519</a>	05/16/2014
<a href="#">XI-200 Clinical Chemistry Analyzer, Jas</a>	Jas Diagnostics, Inc.	<a href="#">K130915</a>	05/15/2014
<a href="#">Unicel Dxc Synchron Systems Glucose Reag</a>	Beckman Coulter, Inc.	<a href="#">K131189</a>	04/17/2014
<a href="#">Ace Alera Clinical Chemistry System, Ace</a>	Alfa Wassermann Diagnostic Technologies,	<a href="#">K123018</a>	04/23/2013
<a href="#">Ace Axcel Clinical Chemistry System, Ace</a>	Alfa Wassermann Diagnostic Technologies,	<a href="#">K113253</a>	05/17/2012
<a href="#">Advia Chemistry Gluh 3 Reagents</a>	Siemens Healthcare Diagnostics Inc.	<a href="#">K120681</a>	05/15/2012

Decision Summary

E. Applicant:

Abbott Laboratories

F. Proprietary and Established Names:

Alinity c Glucose Reagent Kit

Alinity c System

G. Regulatory Information:

1. Regulation section:

Device	Product Code	Classification	Regulation	Panel
Alinity c Glucose Reagent Kit	CFR	Class II	CFR 862.1345 Glucose test system	Clinical Chemistry (75)
Alinity c System	JJE	Class I	CFR 862.2160 Discrete photometric chemistry analyzer for clinical use	



1. Regulatory Context
2. Essential Processes
3. Resources



# Reviewing predicate De novos and Decision Summaries can help

## Device Classification under Section 513(f)(2)(de novo)

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

Search Database

DeNovo Number

510(K) Number

Panel Microbiology

Center

Decision Date

Sort by

Product Code

Priority Review

Device Name

Requester Name

1 to 10 of 31 Results

[Microbiology Decision Date To:](#)  
[2018 de novo Products: Yes](#)

[New Search](#)
[Export to Excel](#)
[Download Files](#)
[More About De Novo](#)

Device Name	Requester	De Novo Number	510(K) Number	Decision Date
<a href="#">Genestat mdx Coccidioides Assay</a>	Dxna, Llc	<a href="#">DEN170041</a>		
<a href="#">Id-Fish Plasmodium Genus Test Kit, Id-Fi</a>	Id-Fish Technology, Inc	<a href="#">DEN160025</a>		08/18/2017
<a href="#">Accelerate Pheno System, Accelerate Phen</a>	Accelerate Diagnostics	<a href="#">DEN160032</a>		02/23/2017
<a href="#">Variola Virus Real-Time Pcr Assay</a>	Centers For Disease Control And Preventi	<a href="#">DEN160016</a>		02/06/2017
<a href="#">Bd Max Vaginal Panel, Bd Max Instrument</a>	Geneohm Sciences Canada , Inc (Bd Diagno	<a href="#">DEN160001</a>		10/28/2016
<a href="#">Apas Compact With Urine Analysis Module</a>	Clever Culture Systems Ag	<a href="#">DEN150059</a>		10/06/2016
<a href="#">Amplichek li, Negative And Amplichek li,</a>	Bio-Rad Laboratories	<a href="#">DEN150058</a>		03/28/2016
<a href="#">B.r.a.h.m.s Pct Sensitive Kryptor</a>	B.r.a.h.m.s Gmbh	<a href="#">DEN150009</a>		02/20/2016
<a href="#">Filmarray Meningitis/Encephalitis(Me) Pa</a>	Biofire Diagnostics, Llc	<a href="#">DEN150013</a>		10/08/2015
<a href="#">T2candida And T2dx Instrument</a>	T2 Biosystems, Inc	<a href="#">DEN140019</a>		09/22/2014

Sample

Slope

Intercept

R<sup>2</sup>

Correlation

Test Range

Alinity c System

H. Intended Use:

EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR ID-FISH Plasmodium Genus Test Kit ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit DECISION SUMMARY

A. DEN Number:

DEN160025

B. Purpose for Submission:

Decision Summary

D. Type of Test:

Fluorescence In Situ Hybridization (FISH) assay using fluorescently labeled DNA probes

E. Applicant:

ID-FISH Technology, Inc.

F. Proprietary and Established Names:

ID-FISH Plasmodium Genus Test Kit (PlasG)  
ID-FISH Plasmodium falciparum and P. vivax Combo Test Kit (PlasFV)

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3367

2. Classification:

Class II (Special Controls)

# 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

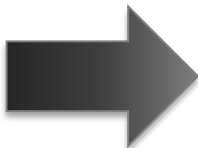
**Review Staff**  
Pre-Submission,  
Interactive Review



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



2018 OIR Submissions Workshop Meeting Agenda

Monday / April 23  
9:00 a.m. – 5:00 p.m.

8:00 – 9:00 a.m. Registration

9:00 – 9:45 Welcome and Registration

9:45 – 10:00 Break

10:00 – 10:30 Presentation: OIR Submissions Process

10:30 – 10:45 Break

10:45 – 11:15 Presentation: OIR Submissions Process

11:15 – 11:45 Break

11:45 – 12:15 Presentation: OIR Submissions Process

12:15 – 1:30 Lunch

1:30 – 2:00 Presentation: OIR Submissions Process

2:00 – 2:30 Presentation: OIR Submissions Process

2:30 – 3:00 Presentation: OIR Submissions Process

3:00 – 3:15 Break

3:15 – 3:45 Presentation: OIR Submissions Process

3:45 – 4:30 Presentation: OIR Submissions Process

4:30 – 5:00 Presentation: OIR Submissions Process

2018 Pre-Submissions Workshop Meeting Agenda

Wednesday / April 25  
8:15 a.m. – 10:30 a.m.

8:15 – 9:00 a.m. Registration

9:00 – 9:45 Welcome and Registration

9:45 – 10:00 Break

10:00 – 10:30 Presentation: Pre-Submissions Process

10:30 – 10:45 Break

10:45 – 11:15 Presentation: Pre-Submissions Process

11:15 – 11:45 Break

11:45 – 12:15 Presentation: Pre-Submissions Process

12:15 – 1:30 Lunch

1:30 – 2:00 Presentation: Pre-Submissions Process

2:00 – 2:30 Presentation: Pre-Submissions Process

2:30 – 2:45 Break

2:45 – 3:30 Presentation: Pre-Submissions Process

3:30 – 4:15 Presentation: Pre-Submissions Process

4:15 – 5:00 Presentation: Pre-Submissions Process

5:00 Presentation: Pre-Submissions Process

5:15 Presentation: Pre-Submissions Process

2018 AMDM Annual Meeting Agenda

Wednesday / April 25  
8:15 a.m. – 10:30 a.m.

8:15 – 9:00 a.m. Registration

9:00 – 9:45 Welcome and Registration

9:45 – 10:00 Break

10:00 – 10:30 Presentation: AMDM Annual Meeting

10:30 – 10:45 Break

10:45 – 11:15 Presentation: AMDM Annual Meeting

11:15 – 11:35 Presentation: AMDM Annual Meeting

11:35 – 12:00 Presentation: AMDM Annual Meeting

12:00 – 1:00 Lunch

1:00 – 1:30 Presentation: AMDM Annual Meeting

1:45 – 2:25 Presentation: AMDM Annual Meeting

2:25 – 3:00 Presentation: AMDM Annual Meeting

3:00 – 3:15 Presentation: AMDM Annual Meeting

## 2018 Educational Workshop & Meeting

10:30 – 10:45	Break
10:45 – 11:15	Replacement Reagent and Instrument Family Policy Guidance Ava Darnovsky, CDRI, FDA - <a href="mailto:ava.darnovsky@fda.hhs.gov">ava.darnovsky@fda.hhs.gov</a>
11:15 – 11:35	De Novo Process Experience Karin Hughes, Vice President Clinical & Regulatory Strategy, Artile Medical, Inc. - <a href="mailto:khughes@artilemedical.com">khughes@artilemedical.com</a>
11:35 – 12:00	Companion Diagnostics Experience Lesley Farrington, Director of Global Regulatory Affairs Diagnostics, Janssen - <a href="mailto:lfarrington@janssen.com">lfarrington@janssen.com</a>
12:00 – 1:00	Lunch
1:00 – 1:30	Program for FDA-CMS Parallel Review: What You Need to Know Rochelle Fink, CDRI, FDA - <a href="mailto:Rochelle.Fink@fda.hhs.gov">Rochelle.Fink@fda.hhs.gov</a>
1:45 – 2:25	Reimbursement: Understanding Key Concepts to Maximize Business Success Tom Hughes, Sr. Principal Advisor Health Economics & Reimbursement, ACB - <a href="mailto:thughes@acbi.com">thughes@acbi.com</a>
2:25 – 3:00	IVDR Update Juli Smith, VP, In Vitro Diagnostics & Quality, Precision for Medicine - <a href="mailto:juli.smith@precisionformedicine.com">juli.smith@precisionformedicine.com</a>
3:00 – 3:15	Review & Wrap Up Ann Quirey, Karen Richards, Carol Ryerson, Meeting Co-Chairs

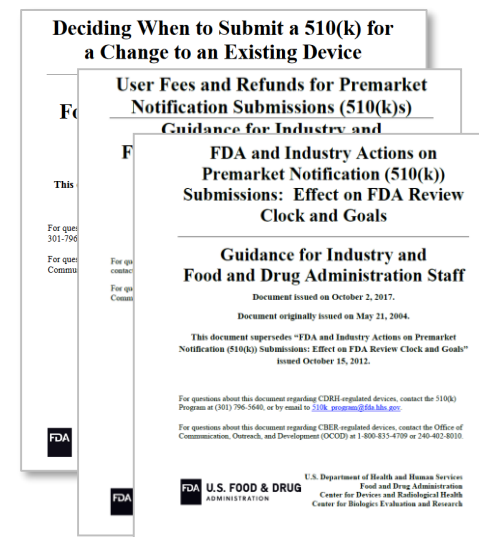
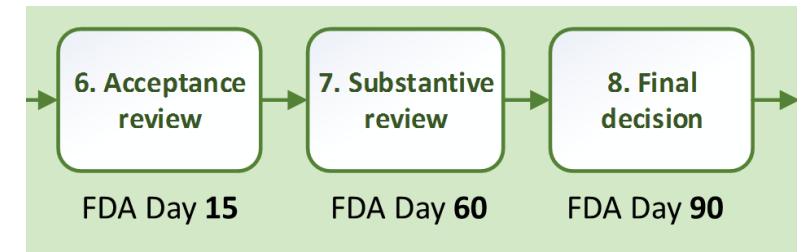
# Understanding 510(k)s begins with three key concepts



## 1. Regulatory Context

## 2. Essential Processes

## 3. Resources





# QUESTIONS AND DISCUSSION

# **APPENDIX**

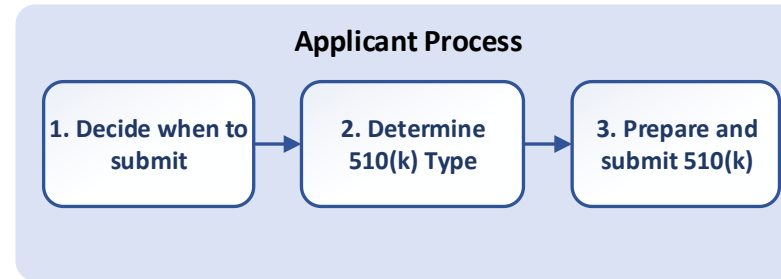
# 510(k) Guidance Links

## Review Standard



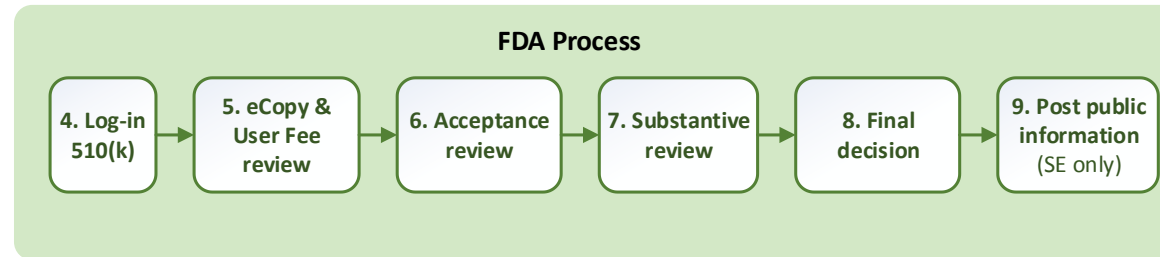
- **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** (<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284443.pdf> )
- **The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles** (<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationand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



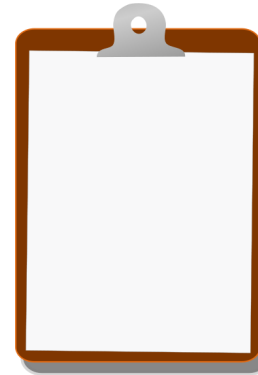
- **eCopy Program for Medical Device Submissions**  
(<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf> )
- **User Fees and Refunds for Premarket Notification Submissions (510(k)s)**  
(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345931.pdf>)
- **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> )



# Image attributions



“Que\_es” from PowerPoint 2010 ClipArt library; search term “decide”



“Clipboard 01”;  
[https://commons.wikimedia.org/wiki/File:Clipboard\\_01.svg](https://commons.wikimedia.org/wiki/File:Clipboard_01.svg); This file is made available under the [Creative Commons CC0 1.0 Universal Public Domain Dedication](#)



“[Search to Find Internet Magnifying Glass Cache](#)”, released under [Creative Commons CC0](#); (“Free for commercial use. Link referral required”)



“Full\_Spectrum\_Team\_Waving” from PowerPoint 2010 ClipArt library; search term “team”



Derivative of “[Search to Find Internet Magnifying Glass Cache](#)”, released under [Creative Commons CC0](#), by Sara Aguel



“question2-300x300” from PowerPoint 2010 ClipArt library; search term “question”

# Image attributions



<https://commons.wikimedia.org/wiki/File:Lime-Whole-Split.jpg>; This file is made available under the [Creative Commons CC0 1.0 Universal Public Domain Dedication](#)



<https://commons.wikimedia.org/wiki/File:Orange-Whole-%26-Split.jpg>; This file is licensed under the [Creative Commons Attribution-Share Alike 3.0 Unported](#) license.



[https://upload.wikimedia.org/wikipedia/commons/d/d2/First\\_Place\\_Blue\\_Ribbon.png](https://upload.wikimedia.org/wikipedia/commons/d/d2/First_Place_Blue_Ribbon.png); This file is licensed under the [Creative Commons Attribution-Share Alike 3.0 Unported](#) license.