

# 10 Steps to Preparing your 510(k) Submission (And How to Avoid the Common Pitfalls)

Allison C. Komiyama, PhD, RAC  
akomiyama@acknowledge-rs.com  
Acknowledge-RS.com

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# Today's Goals

- ▶ Step 1: Know about devices/510(k)s/and substantial equivalence
- ▶ Step 2: Know your device
- ▶ Step 3: Get to know your predicate(s)
- ▶ Step 4: Understand what needs to go into your 510(k)
- ▶ Step 5: Understand what *doesn't* need to go into your 510(k)
- ▶ Step 6: Submit your small business designation request
- ▶ Step 7: Don't mess up your User Fee or eCopy
- ▶ Step 8: Understand the 510(k) review process
- ▶ Step 9: Listen to your reviewer
- ▶ Step 10: Don't pester your reviewer

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# What is a Medical Device?

A device is:

- ▶ "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - ▶ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - ▶ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - ▶ intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

# What is a 510(k)?

## 21 U.S.C.

United States Code, 2010 Edition

Title 21 - FOOD AND DRUGS

CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V - DRUGS AND DEVICES

Part A - Drugs and Devices

Sec. 510 - §360 Registration of producers of drugs or devices

### **(k) Report preceding introduction of devices into interstate commerce**

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)...

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“We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**”



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# What are the regulations for Medical Devices?

There are ~1800 generic groups of devices

▶ Devices are classified within 16 medical specialties

▶ 21 CFR 862-892

862: Clinical Chemistry/Toxicology

864: Hematology and Pathology

866: Immunology and Microbiology

868: Anesthesiology

870: Cardiovascular

872: Dental

874: Ear, Nose and Throat

876: Gastroenterology-Urology

878: General and Plastic Surgery

880: General Hospital and Personal Use

882: Neurological

884: Obstetrical and Gynecological

886: Ophthalmic

888: Orthopedic

890: Physical Medicine

892: Radiology



What does FDA use to decide SE? - FDA Guidance

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**The 510(k) Program: Evaluating  
Substantial Equivalence in Premarket  
Notifications [510(k)]**

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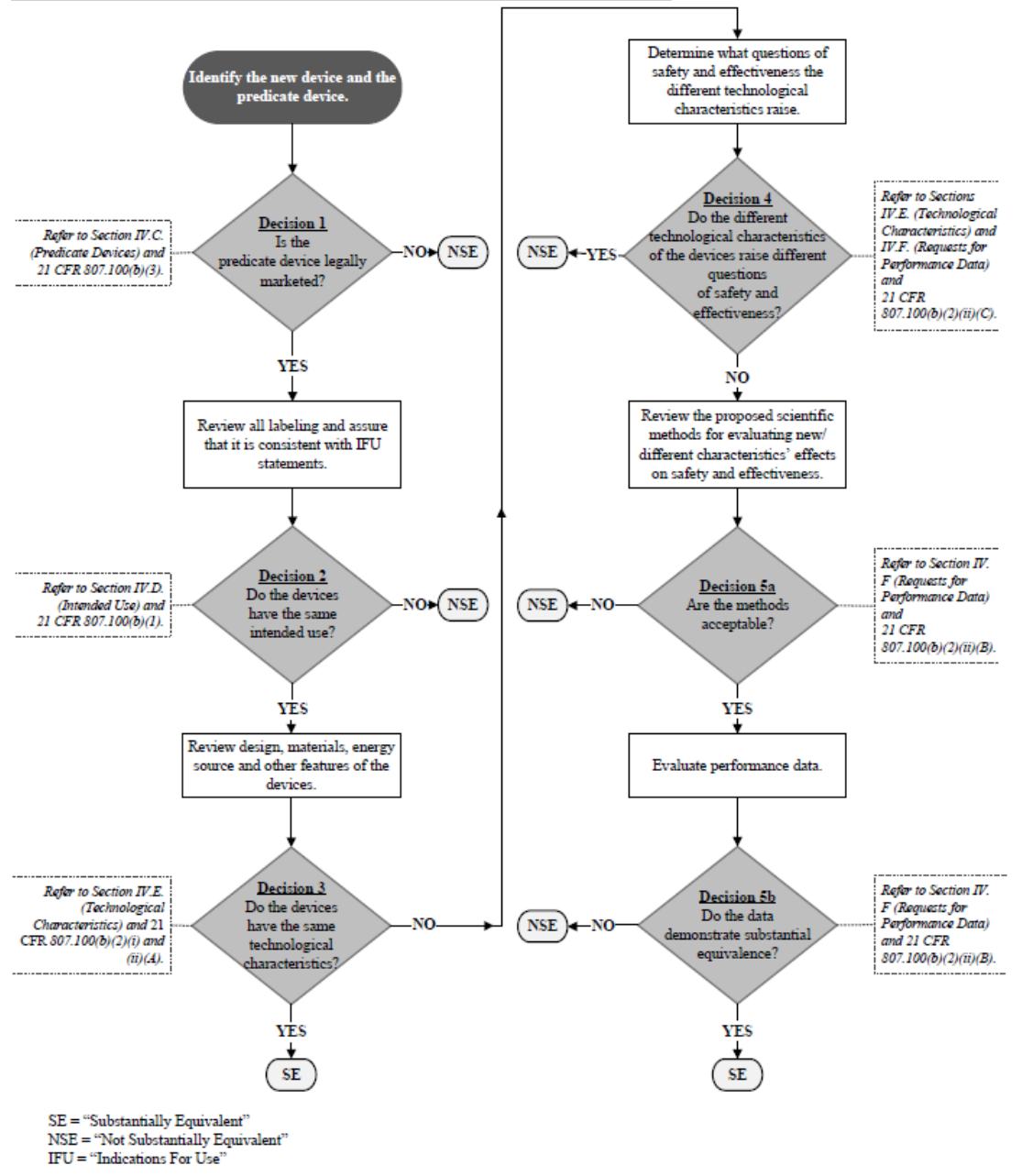
**Guidance for Industry and Food and Drug  
Administration Staff**

**Document issued on: July 28, 2014**

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## Appendix A. 510(k) Decision-Making Flowchart



# What does FDA use to decide SE? - FDA Databases

The screenshot displays the FDA website's interface for the Code of Federal Regulations (CFR) Title 21. At the top, the U.S. Department of Health & Human Services logo is visible, along with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar and a "SEARCH" button are located in the top right. Below the header, a navigation menu includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "CFR - Code of Federal Regulations Title 21" and includes a breadcrumb trail: FDA Home > Medical Devices > Databases. A warning icon and text state: "This information is current as of April 1, 2015. This online reference for CFR Title 21 is updated once a year. For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR). This database includes a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. [Learn More...](#)". Below this is a "Search Database" section with a "Title21 Part.Section (e.g., 862.1385)" label, a "Full Text Search" input field, and a dropdown menu showing categories: (1) General enforcement regulations, (2) General administrative rulings and decisions, (3) Product jurisdiction, (4) Regulation of combination products, and (5) Organization. A "Clear Form" link and a "Search" button are at the bottom of the search section. To the right, an "Other Databases" list includes: 510(k)s, De Novo, Medical Device Reports (MAUDE), CDRH FOIA Electronic Reading Room, CLIA, Device Classification, Humanitarian Device Exemption, Medsun Reports, Premarket Approvals (PMAs), Post-Approval Studies, Postmarket Surveillance Studies, Radiation-Emitting Products, Radiation-Emitting Electronic Products Corrective Actions, Recalls, Registration & Listing, Standards, Total Product Life Cycle, and X-Ray Assembler.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

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# Know Your Device: A Case Study

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## 510(k) Premarket Notification

FDA Home > Medical Devices > Databases

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.  
[Learn more...](#)

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510K Number  Type  [Product Code](#)

Center  Combination Products

Applicant Name  Cleared/Approved In Vitro Products

Device Name

Panel  Third Party Reviewed

Decision

Decision Date  to  Clinical Trials

Sort by  Decision Date (descending)

[Quick Search](#) [Clear Form](#)

**Other Databases**

- De Novo
- Medical Device Reports (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
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- Registration & Listing
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- Total Product Life Cycle
- X-Ray Assembler

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

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510K Number  Type

Center  Product Code

Applicant Name  Combination Products

Device Name  Cleared/Approved In Vitro Products

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Decision Date  to  Clinical Trials

Sort by

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Device Name	Applicant	510(K) Number	Decision Date
<a href="#">Medical Maggots, Lesoc</a>	Monarch Labs, Llc.	<b><a href="#">K102827</a></b>	11/02/2011
<a href="#">Medical Maggots, Creature Comforts</a>	Monarch Labs, Llc.	<a href="#">K072438</a>	10/05/2007
<a href="#">Medical Maggots</a>	Ronald A. Sherman	<a href="#">K033391</a>	01/12/2004



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<b>Device Classification Name</b>	<a href="#">Maggots, Medical</a>
<b>510(k) Number</b>	K102827
<b>Device Name</b>	MEDICAL MAGGOTS, LESOC
<b>Original Applicant</b>	MONARCH LABS, LLC. 17875 Sky Park Circle, Suite K Irvine, CA 92614
<b>Original Contact</b>	Ronald Sherman
<b>Classification Product Code</b>	<a href="#">NQK</a>
<b>Date Received</b>	09/29/2010
<b>Decision Date</b>	11/02/2011
<b>Decision</b>	Substantially Equivalent (SESE)
<b>510k Review Panel</b>	General & Plastic Surgery
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Special
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

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## 510(k) Summary

Date Prepared: September 14, 2010, updated January 28, 2011.

### 1. Product name and description

- a) **Scientific name:** *Phaenicia sericata* larvae (see Figure 1)
- b) **Common names:** Maggot dressings; green blow fly maggots; disinfected maggots; sterile maggots; therapeutic maggots; debriding maggots; maggot debridement therapy. Accessories: MDT dressings; maggot confinement dressings; maggot cage dressings.
- c) **“Proprietary” name:** Medical Maggots; to be used with Creature Comforts or LeSoc (the latter being the new accessory featured in this Special PMN)
- d) **Name and 510(k) number of legally marketed device:**
  - Medical Maggots and associated dressings (including Creature Comforts & Creature Comforts Nylon Stockings); K033391.
  - Medical Maggots and associated dressings (including LeFlap dual-layered dressing); K072438.



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## 5. Studies demonstrating substantial equivalence

Evidence of substantial equivalence was based on results of the following evaluations:

Penetration & Durability Feasibility Study, which demonstrated that maggots would not escape during normal operation.

Sterilization validation, which demonstrated steam sterilization to be an adequate method of sterilization.

Biocompatibility testing (data supplied by manufacturer), which demonstrated the material not to be toxic nor to induce contact hypersensitivity in mice.

## 6. Intended use of the device (Indications: unchanged)


Medical Maggots are indicated for debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post surgical wounds.

The accessory maggot confinement dressings, Creature Comforts™, and LeFlap™ and LeSoc™, are indicated for confining the medicinal maggots on the area of treatment during debridement therapy for the conditions mentioned above.

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<b>Classification Product Code</b>	<a href="#">NQK</a> 
<b>Date Received</b>	09/29/2010
<b>Decision Date</b>	11/02/2011
<b>Decision</b>	Substantially Equivalent (SESE)
<b>510k Review Panel</b>	General & Plastic Surgery
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Special
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

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510K Number  Type

Center

Applicant Name

Device Name

Panel

Decision

Decision Date  to

Sort by

Product Code **NQK**

Combination Products

Cleared/Approved In Vitro Products

Third Party Reviewed

Clinical Trials

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

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Device Name	Applicant	510(K) Number	Decision Date
<a href="#">Larval Debridement Therapy Products - La</a>	Biomonde	<a href="#">K142020</a>	11/05/2014
<a href="#">Larval Debridement Therapy Products - Bi</a>	Biomonde	<a href="#">K131221</a>	08/28/2013
<a href="#">Biomonde Larvae</a>	Biomonde (A Trading Name Of Zoobiotic Li	<a href="#">K123449</a>	03/05/2013
<a href="#">Medical Maggots, Lesoc</a>	Monarch Labs, Llc.	<a href="#">K102827</a>	11/02/2011
<a href="#">Medical Maggots, Creature Comforts</a>	Monarch Labs, Llc.	<a href="#">K072438</a>	10/05/2007
<a href="#">Medical Maggots</a>	Ronald A. Sherman	<b>K033391</b>	01/12/2004

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<a href="#">New Search</a>	<a href="#">Back To Search Results</a>
<b>Device Classification Name</b>	<a href="#">Maggots, Medical</a>
<b>510(k) Number</b>	K033391
<b>Device Name</b>	MEDICAL MAGGOTS
<b>Original Applicant</b>	RONALD A. SHERMAN 36 Urey Court Irvine, CA 92612
<b>Original Contact</b>	Ronald A Sherman
<b>Classification Product Code</b>	<a href="#">NQK</a>
<b>Date Received</b>	10/23/2003
<b>Decision Date</b>	01/12/2004
<b>Decision</b>	Substantially Equivalent (SESE)
<b>510k Review Panel</b>	General & Plastic Surgery
<b>Statement</b>	<a href="#">Statement</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

# Know Your Predicate - A Case Study

Mr. Ronald A. Sherman  
36 Urey Court  
Irvine, California 92612

Re: K033391  
Trade/Device Name: Medical Maggots  
Regulatory Class: Unclassified  
Product Code: NQK  
Dated: October 16, 2003  
Received: October 23, 2003

510(k) Number (if known):           K033391  
Device Name:                            Medical Maggots

indications For Use:

For debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post surgical wounds.



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# Know Your Predicate - A Case Study

## 21 CFR 807.93

New Search Help | More About 21CFR

[Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2013]  
[CITE: 21CFR807.93]

 See Related Information

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 807 -- ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

Subpart E--Premarket Notification Procedures

Sec. 807.93 Content and format of a 510(k) statement.

(a) (1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

# Know Your Predicate - A Case Study

August 8, 2019  
Medical Maggots  
Attn: Ronald A. Sherman  
Re: Request for duplicate 510(k) Premarket Notification, K033391

Dear Dr. Sherman,

Pursuant to Section 510(k) of the Food, Drug and Cosmetics Act and 21 CFR Part 807.93, AcKnowledge Regulatory Strategies, LLC hereby requests a duplicate copy of your premarket notification for Medical Maggots (K033391) cleared on January 4, 2004.

In the 510(k) Statement of your submission, you agreed to make available a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifier, trade secret, and confidential commercial information, as defined in 21 CFR 20.61. You have stated that this information will be made available within 30 days of our request.

Please send the submission to:

Attn: Allison Komiyama  
AcKnowledge Regulatory Strategies, LLC  
2251 San Diego Avenue, Suite B-257  
San Diego, CA 92110  
Phone: (619) 458-9547  
Email: [akomiyama@acknowledge-rs.com](mailto:akomiyama@acknowledge-rs.com)

Please call me if you have any questions regarding this request.

Best Regards,

**Allison Komiyama, Ph. D., R.A.C.**  
Principal Consultant

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The screenshot shows the FDA's FOIA website. At the top, it features the U.S. Department of Health & Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". There is a search bar with a "SEARCH" button and a "Most Popular Searches" section. A navigation menu includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products.

## FDA Freedom of Information Act (FOIA)

FDA Home

### FDA FOIA On-Line Request Submission Information

- All Required (\*) fields must be completed before submitting your request
- A valid e-mail address is required.
- A complete description of your request must be in the Subject field.
- An electronic copy of your Request letter may be attached to the Request form.
- Multiple request may be entered without re-entering the Requester information.
- After submitting a request you will be given a confirmation # and the ability to print copy of your request.
- After acceptance by FDA FOI staff an electronic Acknowledgement letter with your FOI Control # will be sent to the e-mail address provided in the Request
- This form is for submission of FOIA Request by members of the public. Do not use this form to submit Consumer Complaints, or if you are seeking records as a representative of a national, state or local government.
- Please include as much detail as possible about the specific records you are requesting.

**Frequent Requester\***

Email:

Password:  [Submit](#)

**New Requester**

[Request Form](#)

\* If you submit FOI requests frequently to FDA and have an FOI account please enter your Email and Password and select the Submit link.

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Understand what needs to go into your 510(k)

# **Guidance for Industry and FDA Staff**

## **Format for Traditional and Abbreviated 510(k)s**

**Document issued on: August 12, 2005**

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# Understand what needs to go into your 510(k)

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

# Understand what needs to go into your 510(k)

- ▶ 1. Medical Device User Fee Cover Sheet
- ▶ 2. CDRH Premarket Review Submission Cover Sheet
- ▶ 3. 510(k) Cover Letter & RTA Checklist
- ▶ 4. Indications for Use Statement & Comparison to Predicate Indications
- ▶ 5. 510(k) Summary or 510(k) Statement
- ▶ 6. Truthful and Accuracy Statement
- ▶ 7. Class III Summary and Certification
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- ▶ 13. Proposed Labeling
- ▶ 14. Cleaning, Reprocessing, Sterilization and Shelf Life
- ▶ 15. Biocompatibility & Tox Assessments
- ▶ 16. Software & Cybersecurity
- ▶ 17. Electromagnetic Compatibility and Electrical Safety
- ▶ 18. Performance Testing – Bench
- ▶ 19. Performance Testing – Animal
- ▶ 20. Performance Testing – Clinical
- ▶ 21. Other (Previous Interactions w. FDA, Usability/Human Factors, RWE)

# Understand what needs to go into your 510(k)

- ▶ 1. Medical Device User Fee Cover Sheet
- ▶ 2. CDRH Premarket Review Submission Cover Sheet
- ▶ 3. 510(k) Cover Letter & RTA Checklist
- ▶ 4. Indications for Use Statement & Comparison to Predicate Indications
- ▶ **5. 510(k) Summary or 510(k) Statement**
- ▶ 6. Truthful and Accuracy Statement
- ▶ 7. Class III Summary and Certification
- ▶ 8. Financial Certification or Disclosure Statement
- ▶ 9. Declarations of Conformity and Summary Reports
- ▶ 10. Executive Summary
- ▶ **11. Device Description**
- ▶ **12. Substantial Equivalence Discussion**
- ▶ **13. Proposed Labeling**
- ▶ 14. **Cleaning, Reprocessing,** Sterilization and Shelf Life
- ▶ 15. Biocompatibility & Tox Assessments
- ▶ 16. Software & Cybersecurity
- ▶ 17. Electromagnetic Compatibility and Electrical Safety
- ▶ 18. Performance Testing – Bench
- ▶ 19. Performance Testing – Animal
- ▶ 20. Performance Testing – Clinical
- ▶ 21. Other (**Previous Interactions w. FDA, Usability/Human Factors, RWE**)



# Understand what doesn't need to go into your 510(k)

(Case Study Continued)



- ▶ 1. Medical Device User Fee Cover Sheet
- ▶ 2. CDRH Premarket Review Submission Cover Sheet
- ▶ 3. 510(k) Cover Letter & RTA Checklist
- ▶ 4. Indications for Use Statement & Comparison to Predicate Indications
- ▶ 5. 510(k) Summary or 510(k) Statement
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- ▶ 16. Software & Cybersecurity
- ▶ 17. Electromagnetic Compatibility and Electrical Safety
- ▶ 18. Performance Testing – Bench
- ▶ 19. Performance Testing – Animal
- ▶ 20. Performance Testing – Clinical
- ▶ 21. Other (Previous Interactions w. FDA, Usability/Human Factors, RWE)

# Today's Goals

- ▶ Step 1: Know about devices/510(k)s/and substantial equivalence

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- ▶ Step 2: Know your device

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- ▶ Step 3: Get to know your predicate(s)

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- ▶ Step 4: Understand what needs to go into your 510(k)

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- ▶ Step 5: Understand what *doesn't* need to go into your 510(k)

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- ▶ **Step 6: Submit your small business designation request**

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- ▶ **Step 7: Don't mess up your User Fee or eCopy**

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- ▶ Step 8: Understand the 510(k) review process

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- ▶ Step 9: Listen to your reviewer

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- ▶ Step 10: Don't pester your reviewer

Submit your small business designation request

# **Medical Device User Fee Small Business Qualification and Certification**

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## **Guidance for Industry, Food and Drug Administration Staff and Foreign Governments**

**Document issued on August 1, 2018.**

★Fun fact:

A small business is defined as a business, including its affiliates, whose gross receipts and sales are less than **\$100 million** for the most recent tax year.”

★Fun fact:

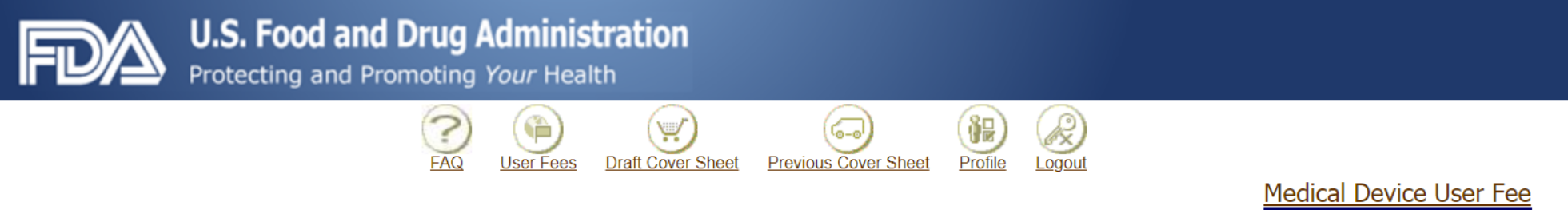
For FY20 a standard 510(k) will cost \$11,594. But if you're a small business, you'll only pay \$2,899. That's a savings of \$8,695!

<https://www.fda.gov/media/93354/download>



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# Don't mess up your User Fee or eCopy



The screenshot shows the top navigation bar of the FDA website. On the left is the FDA logo with the text "U.S. Food and Drug Administration" and "Protecting and Promoting Your Health". To the right of the logo is a horizontal menu with six icons: a question mark (FAQ), a person with a dollar sign (User Fees), a shopping cart (Draft Cover Sheet), a truck (Previous Cover Sheet), a person with a document (Profile), and a person with a key (Logout). The "User Fees" link is highlighted in blue.

## Medical Device User Fee

**FDA will not accept your submission if your company has not paid an establishment registration fee that is due to FDA. Has your company paid all establishment registration fees that are due to FDA?**

- YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
- NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See [Who Must Register, List and Pay the Fee](#) for additional information.)

Medical Device User Fee Cover Sheet      [Application Details](#)

★ Fun fact:

If this is your first device submission and/or don't have a currently marketed device, you might not need to pay a registration fee (FY20 \$5,236) in order to submit your 510(k)!



# Don't mess up your User Fee or eCopy

Cover Sheet	Creation Date	Last Update Date	
<del>FY 2019 Medical Device User Fee Cover Sheet</del> <a href="#">Print/View Final Cover Sheet</a>	1	[REDACTED]	Net: \$10,953.00
			<b>Total: \$10,953.00</b>
<b>Customer Information</b>			
Customer: AcKnowledge Regulatory Strategies Allison Komiyama [REDACTED] akomiyama@acknowledge-rs.com			
<b>Applicant Contact Information</b>			
Bill To: Allison Komiyama AcKnowledge Regulatory Strategies [REDACTED]			

★ Fun fact:

If you don't submit the User Fee Cover Sheet with your 510(k), you will be placed on User Fee Hold. [Ok, maybe *not* such a fun fact.]



# Don't mess up your User Fee or eCopy

## **eCopy Program for Medical Device Submissions**

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### **Guidance for Industry and Food and Drug Administration Staff**

**Document issued on December 3, 2015.**

★Fun fact:

Save a tree and don't send your whole 510(k) to FDA. Add the following to your cover letter: "This Traditional 510(k) Premarket Notification is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy, except only the cover letter and cover sheet have been printed."

# Today's Goals

- ▶ Step 1: Know about devices/510(k)s/and substantial equivalence

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- ▶ Step 2: Know your device

---

- ▶ Step 3: Get to know your predicate(s)

---

- ▶ Step 4: Understand what needs to go into your 510(k)

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- ▶ Step 5: Understand what *doesn't* need to go into your 510(k)

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- ▶ Step 6: Submit your small business designation request

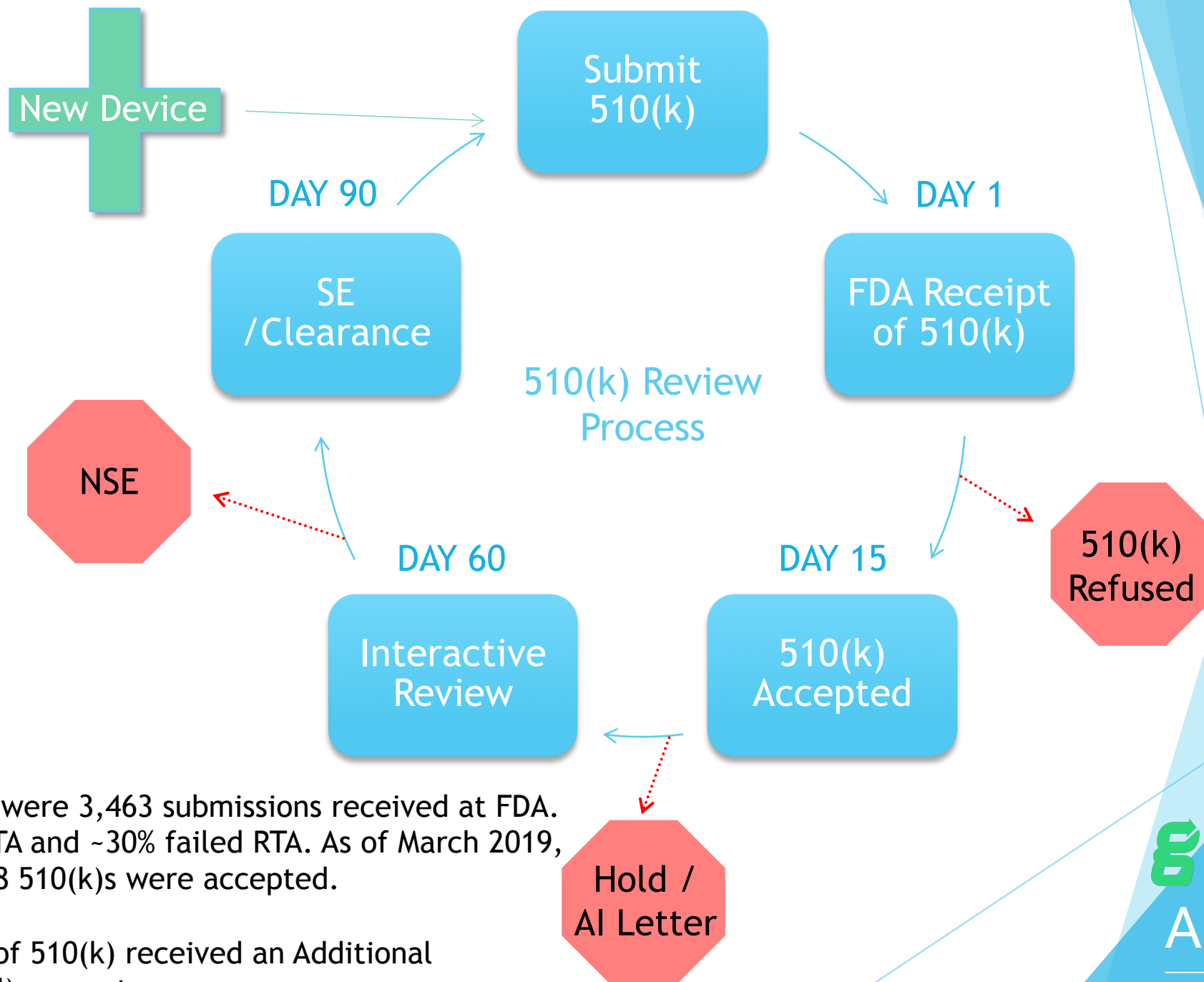
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- ▶ Step 7: Don't mess up your User Fee or eCopy

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- ▶ Step 8: Understand the 510(k) review process
- ▶ Step 9: Listen to your reviewer
- ▶ Step 10: Don't pester your reviewer

# Understand the 510(k) review process



## ★Fun fact:

In FY18, there were 3,463 submissions received at FDA. ~70% passed RTA and ~30% failed RTA. As of March 2019, ~95% of all FY18 510(k)s were accepted.

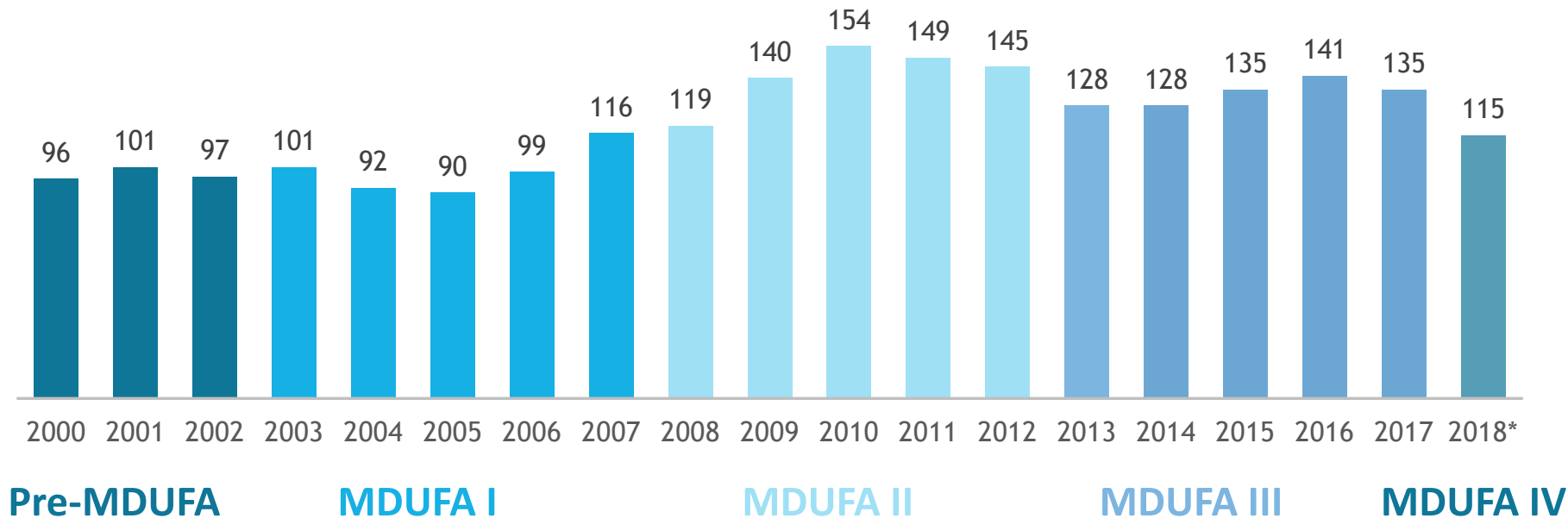
## ★Fun fact:

In FY18, ~65% of 510(k) received an Additional Information (AI) request.



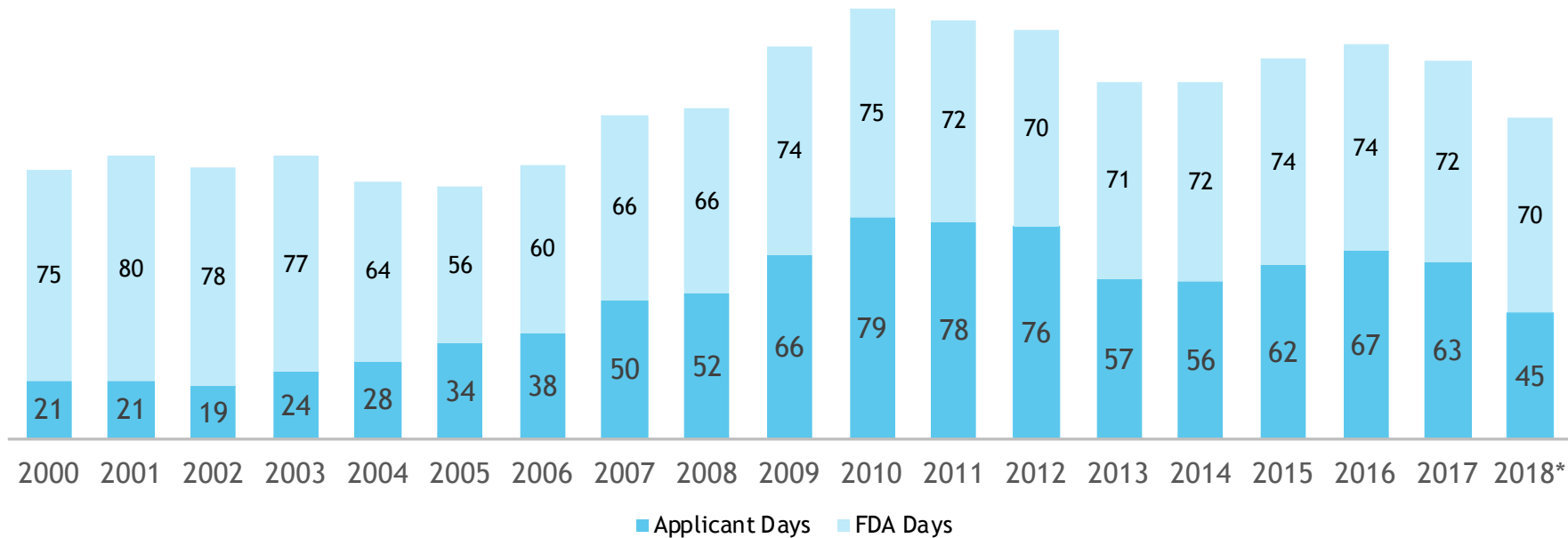
# Understand the 510(k) review process

Average Calendar Days for Traditional 510(k) to Clear  
(as of 3/31/19)



# Understand the 510(k) review process

Average Calendar Days for Traditional 510(k) to Clear  
(as of 3/31/19)



# Understand the 510(k) review process

## FDA Goals Regarding Time to Decision (in days)

	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22
510(k)	135	135	130	130	124	124	120	116	112	108

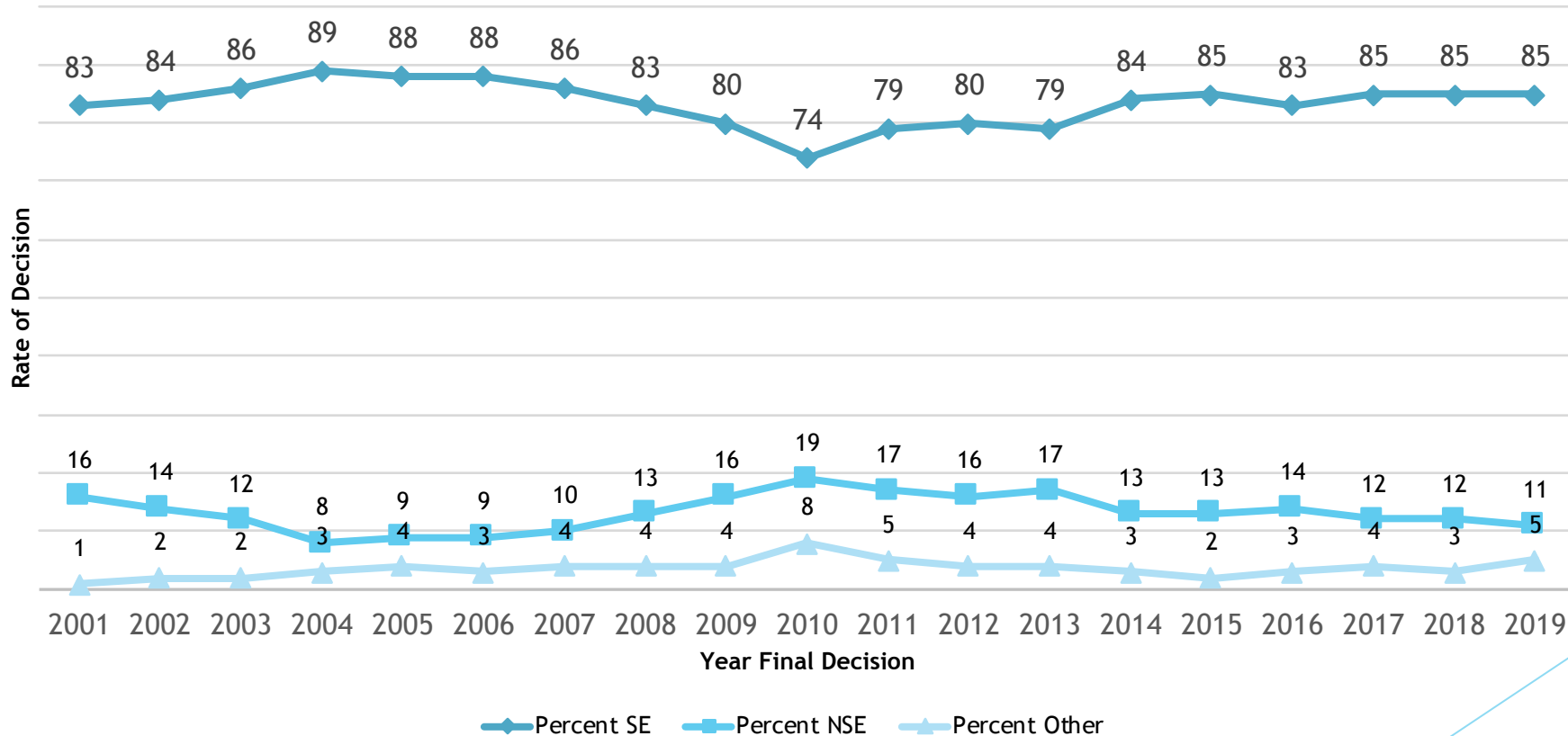
<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>



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# Understand the 510(k) review process

## Rates of SE, NSE and Other Decisions by FY of Decision



# Listen to/Don't pester your reviewer

- ▶ According to the indications for use, your device is indicated for use in debriding non-healing necrotic skin wounds due to zombie bites. You provided bench performance testing for your device along with cadaveric testing. While this information is helpful, your device is intended for use on a dynamic living human. As previously discussed during the teleconference for your Q-Submission (Q190000), you need to provide representative testing that adequately simulates real world use of the device. Please provide a clinically relevant study that evaluates the in vivo response for this specific indication. This testing is requested to evaluate whether the device is as safe as the cited primary predicate when used for non-healing necrotic skin wounds due to zombie bites.
- ▶ We encourage collaboration on clinical safety testing design via the Pre-Submission program. This may help ensure study data are most effective in demonstrating substantial equivalence of the subject and predicate devices.
- ▶ Alternatively, you may choose to remove this indication from your indications for use statement.

# Thank you! Questions?

Allison C. Komiyama, PhD, RAC

[akomiyama@acknowledge-rs.com](mailto:akomiyama@acknowledge-rs.com)

[Acknowledge-RS.com](http://Acknowledge-RS.com)



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