10 Steps to Preparing your 510(k) Submission

(And How to Avoid the Common Pitfalls)

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AcKnowledge-RS.com

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MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

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years industry experience

125k
podcast listeners

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68k
look to us for the latest in quality

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"Great eQMS Software..."

"The software is easy to use with little to no customization needed. It has been a great tool for developing our device through design control. The post-market additions have been amazing as well as tasks. After using multiple types of eQMS software over the years this is the best by far!"

"My QMS is world class" ★★★★★

"Design controls lifesaver" ★★★★★

"One-stop shop" ★★★★★

"Fantastic product, even better team" ★★★★★

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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)
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- Step 7: Don't mess up your User Fee or eCopy
- Step 8: Understand the 510(k) review process
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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."

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

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)…

"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."

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

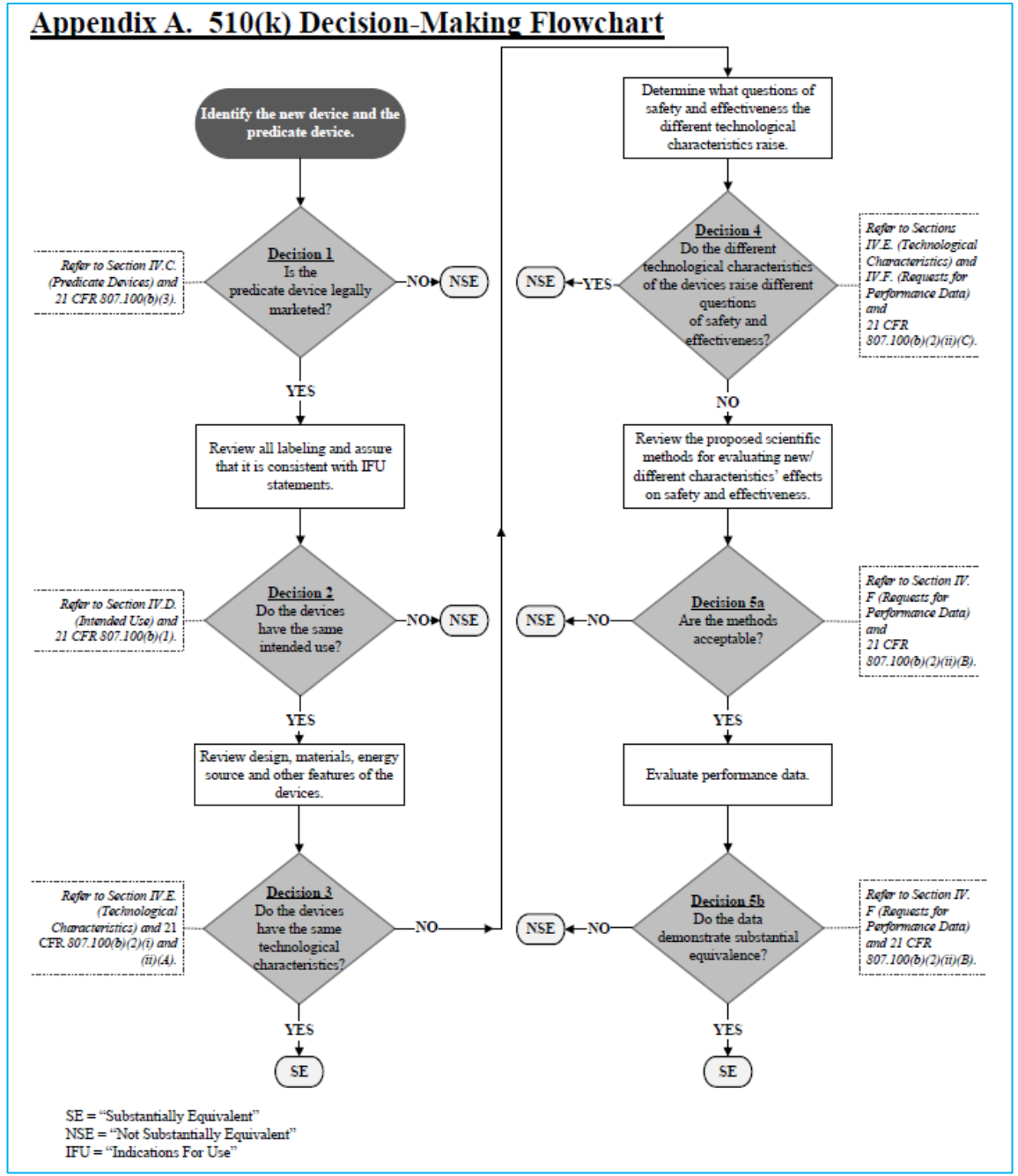
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

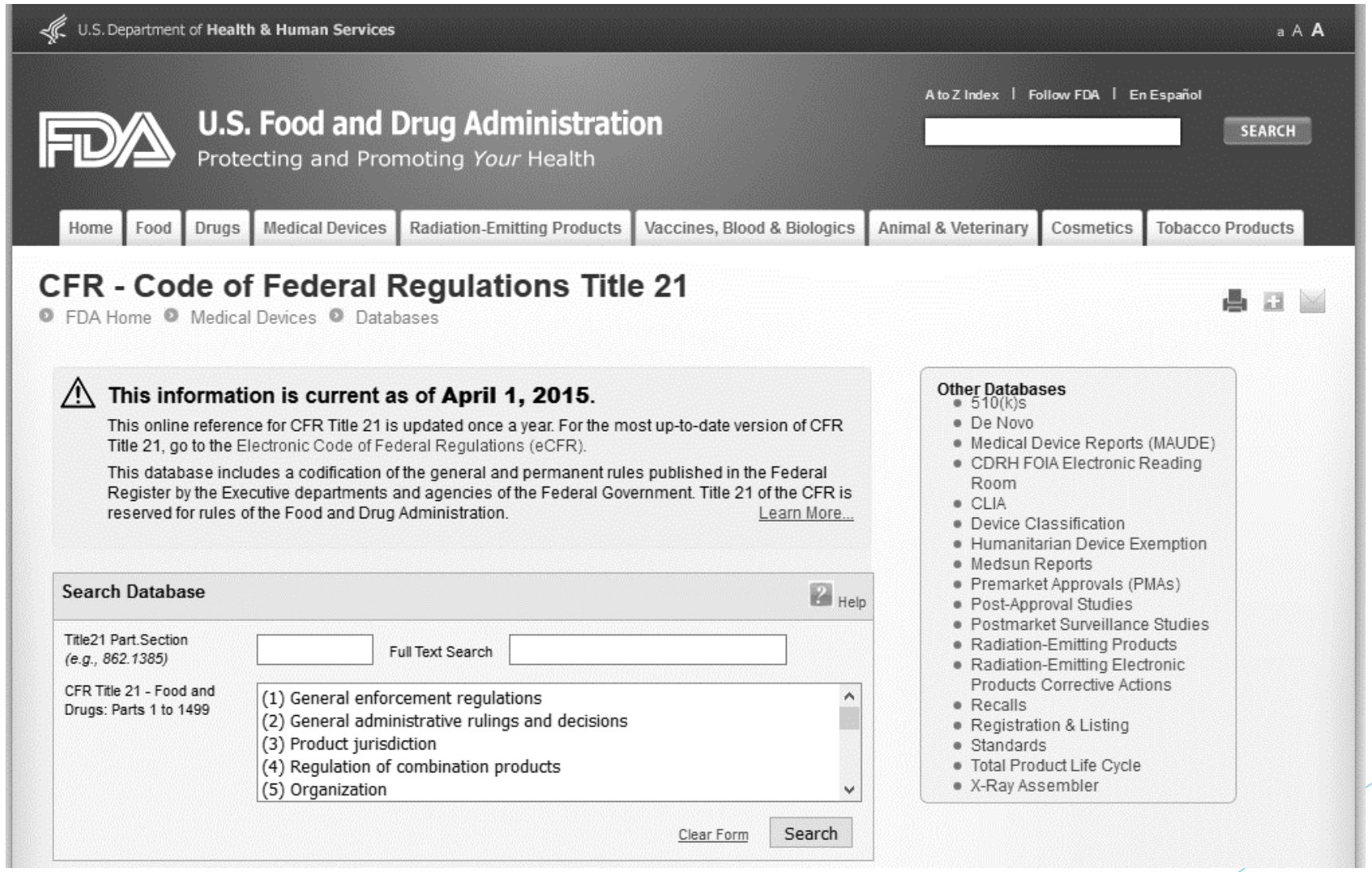
http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284443.pdf

Appendix A. 510(k) Decision-Making Flowchart



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"
IFU = "Indications For Use"

What does FDA use to decide SE? - FDA Databases



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

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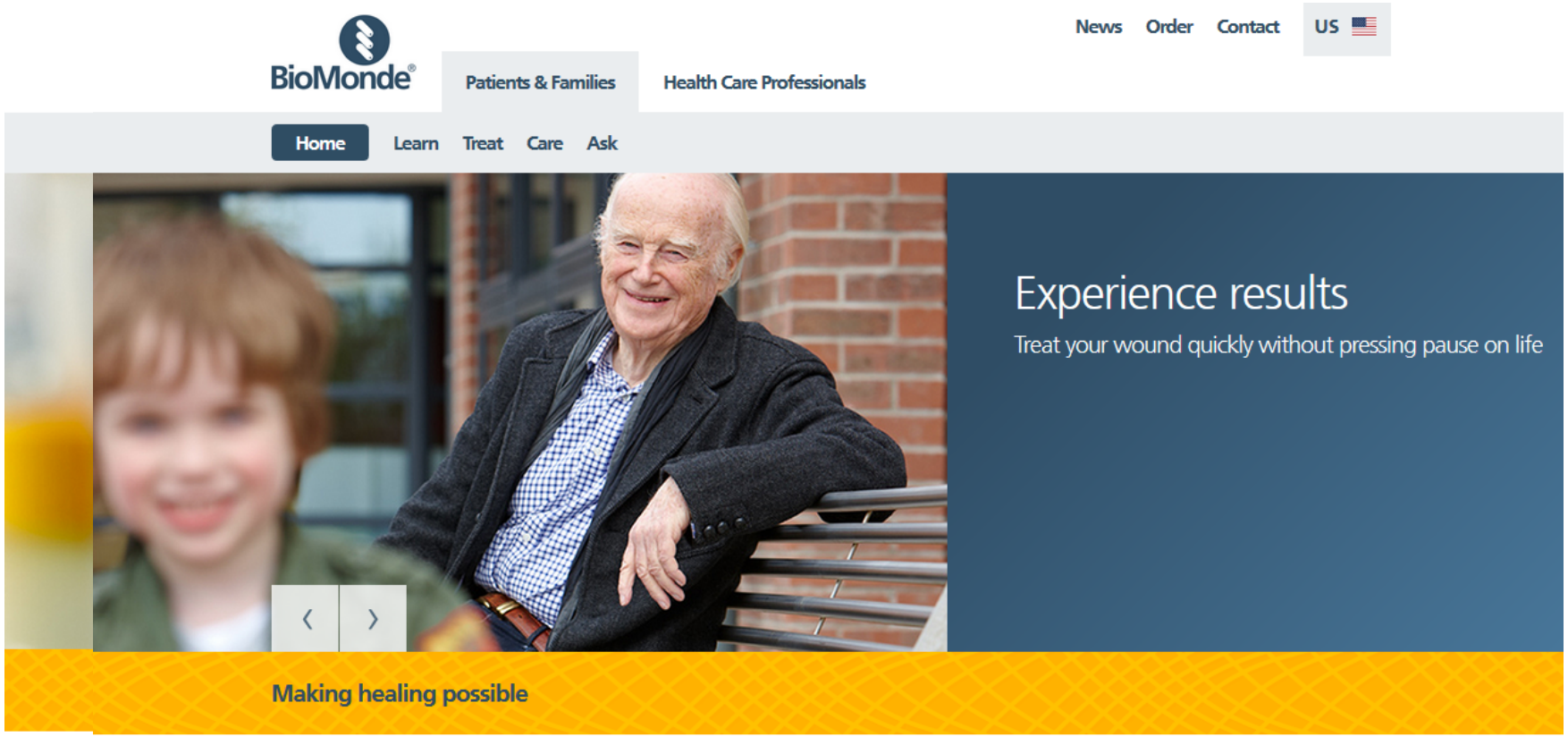
Know Your Device: A Case Study



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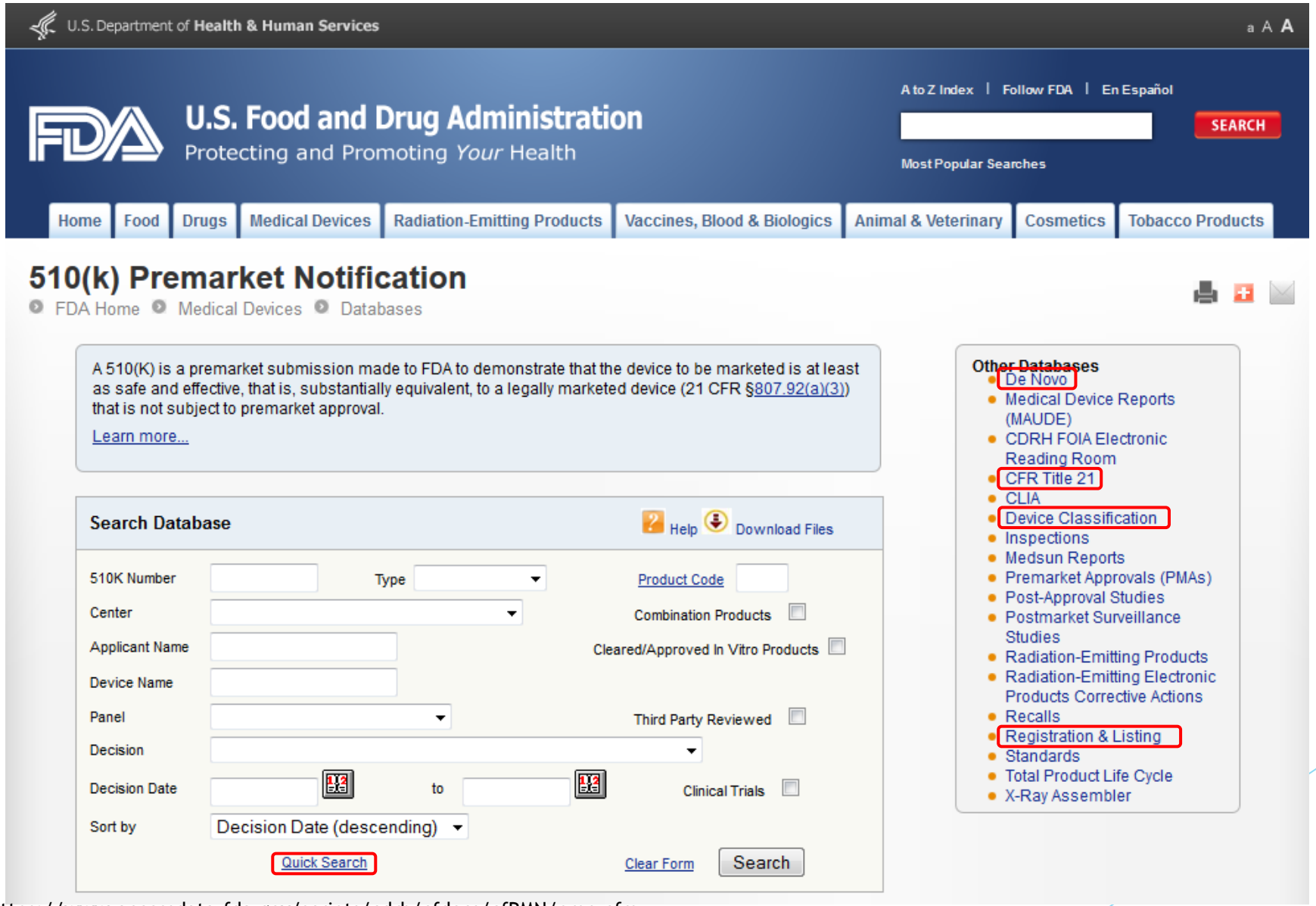

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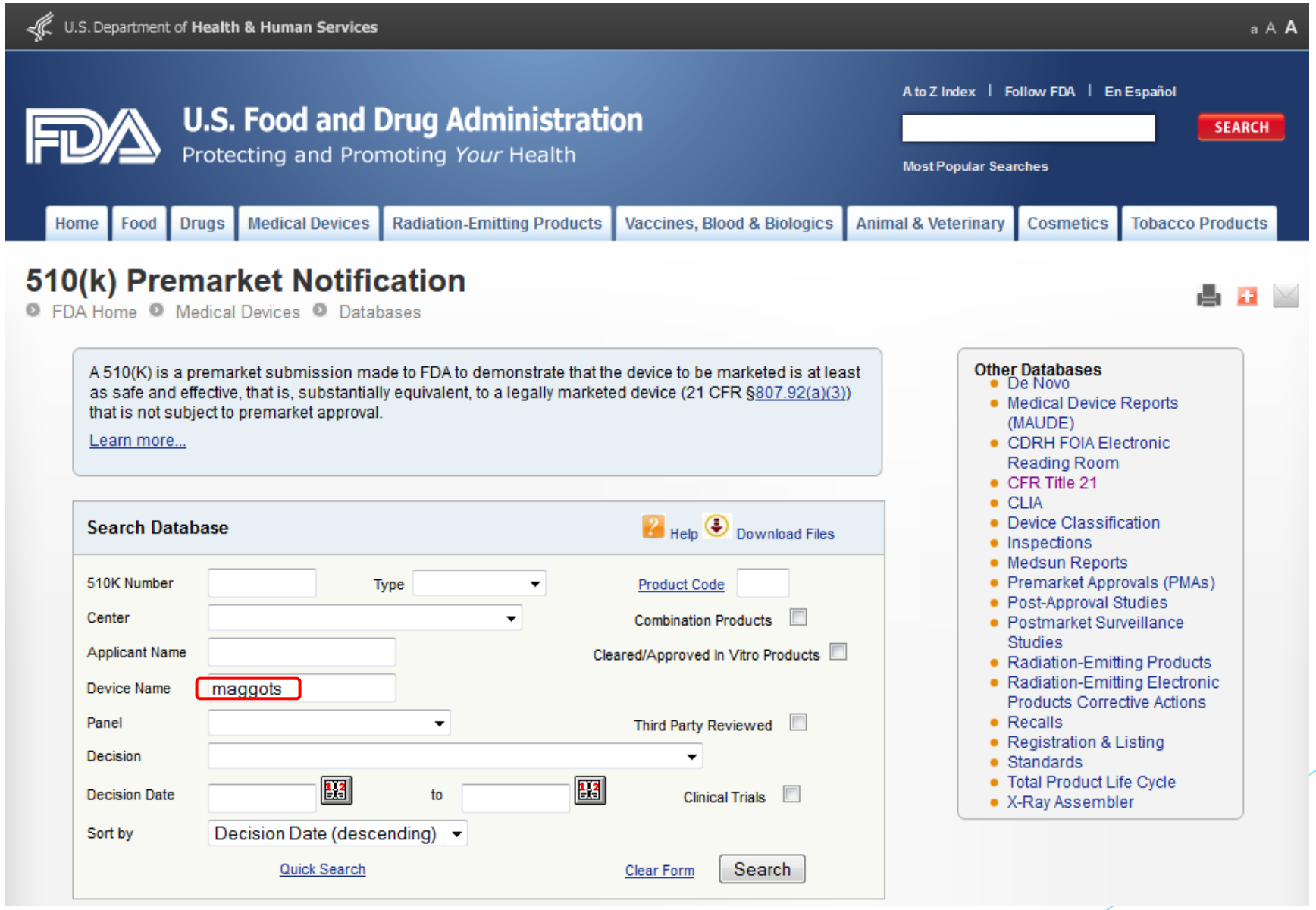

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New Search | Export to Excel | Download Files | More About 510(k)

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

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New Search | Back To Search Results

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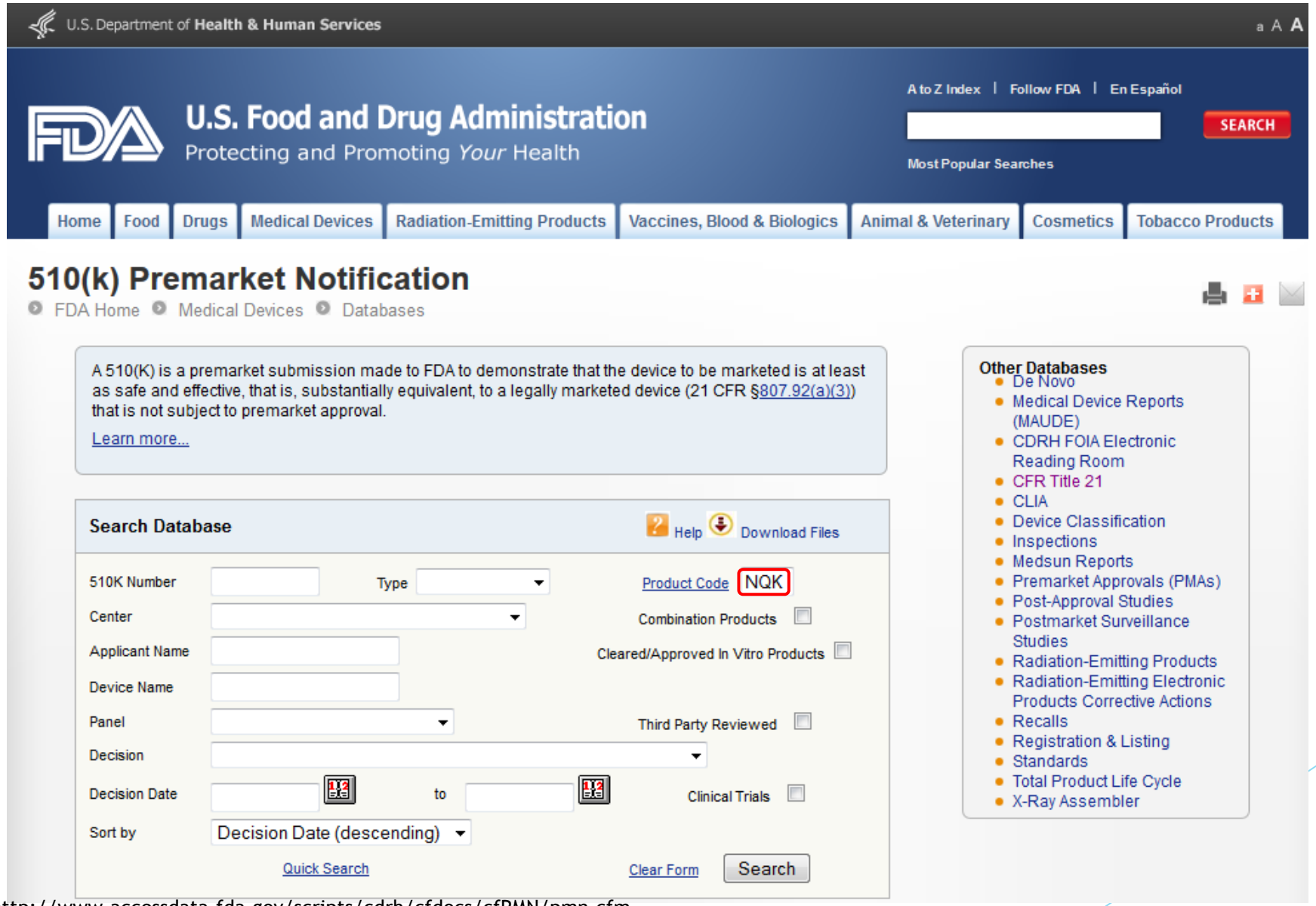

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

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

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New Search | Back To Search Results

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

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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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21 CFR 807.93

New Search | Help | More About 21CFR

See Related Information

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

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

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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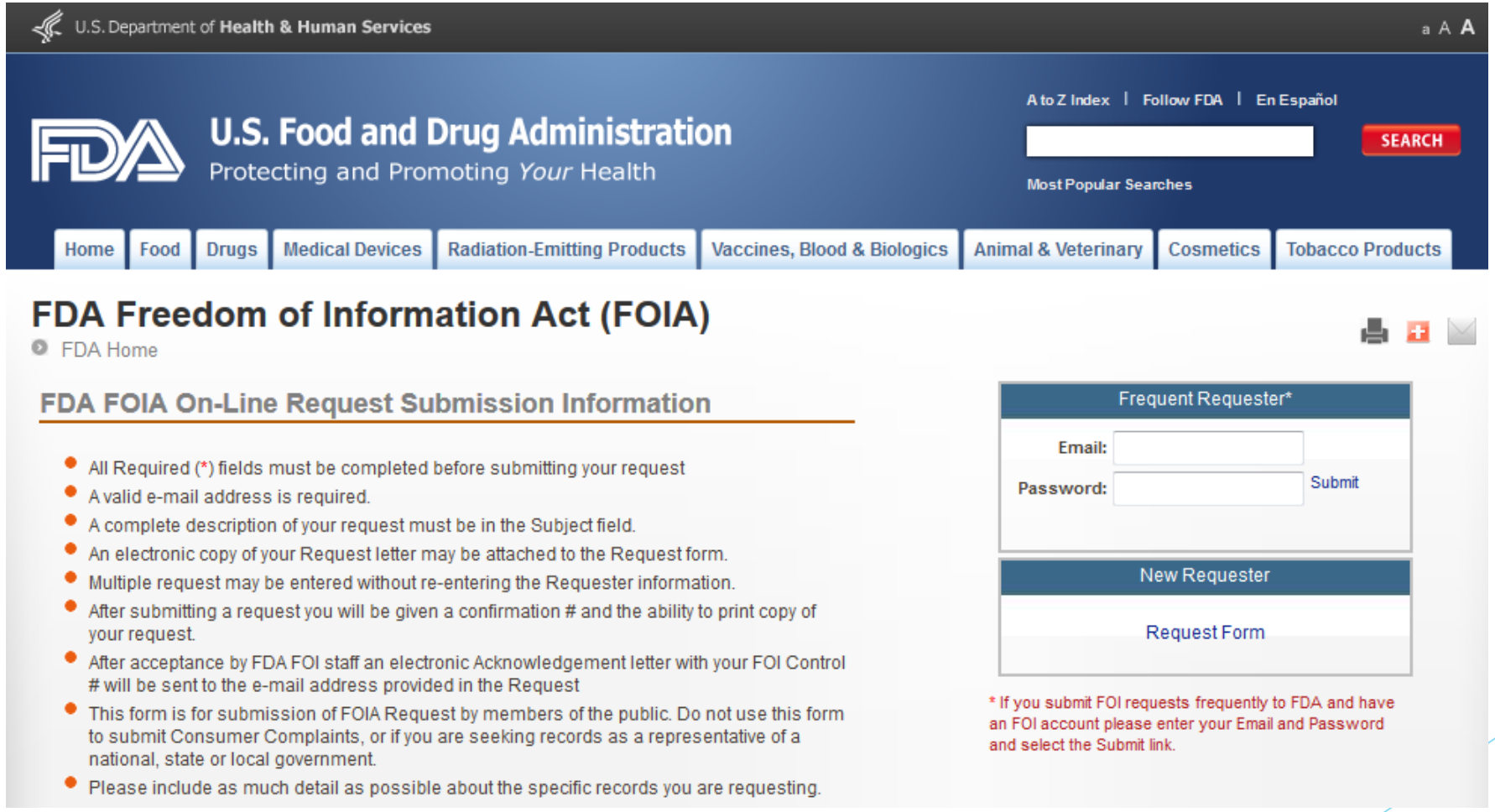

http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm

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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

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks-guidance-industry-and-fda-staff

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

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- 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)

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- 20. Performance Testing – Clinical
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Understand what doesn't need to go into your 510(k)

(Case Study Continued)

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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

★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)!

https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp

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Don’t mess up your User Fee or eCopy

Cover Sheet		Creation Date	Last Update Date	
FY 2019 Medical Device User Fee Cover Sheet Print/View Final Cover Sheet	1	[redacted]		Net: $10,953.00
			Total:	**$10,953.00**

Customer Information

Customer: AcKnowledge Regulatory Strategies
Allison Komiyama
[redacted]
akomiyama@acknowledge-rs.com

Applicant Contact Information

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.]

https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp

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Don’t mess up your User Fee or eCopy

eCopy Program for Medical Device Submissions

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.”

https://www.fda.gov/media/83522/download

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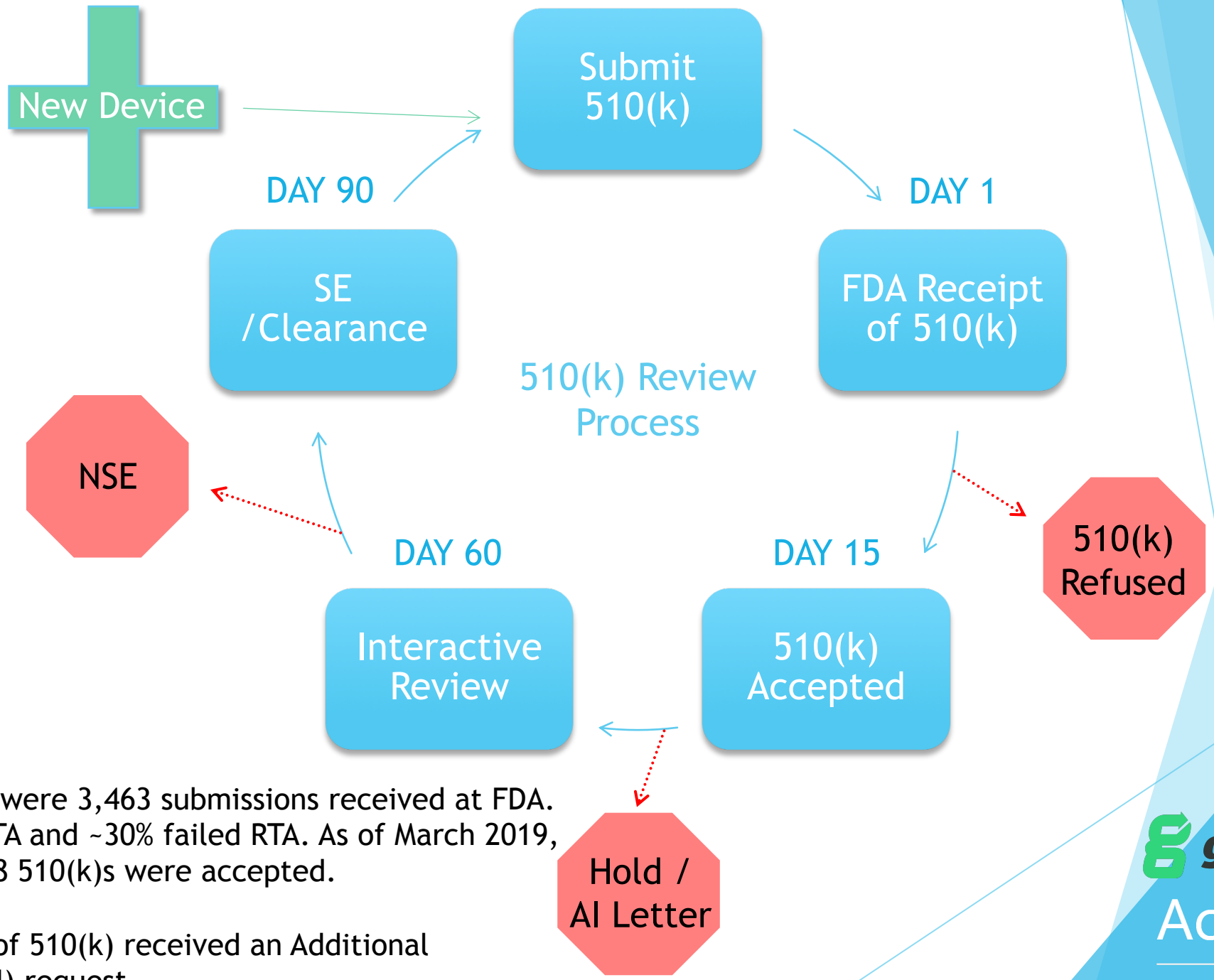
Understand the 510(k) review process



★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.

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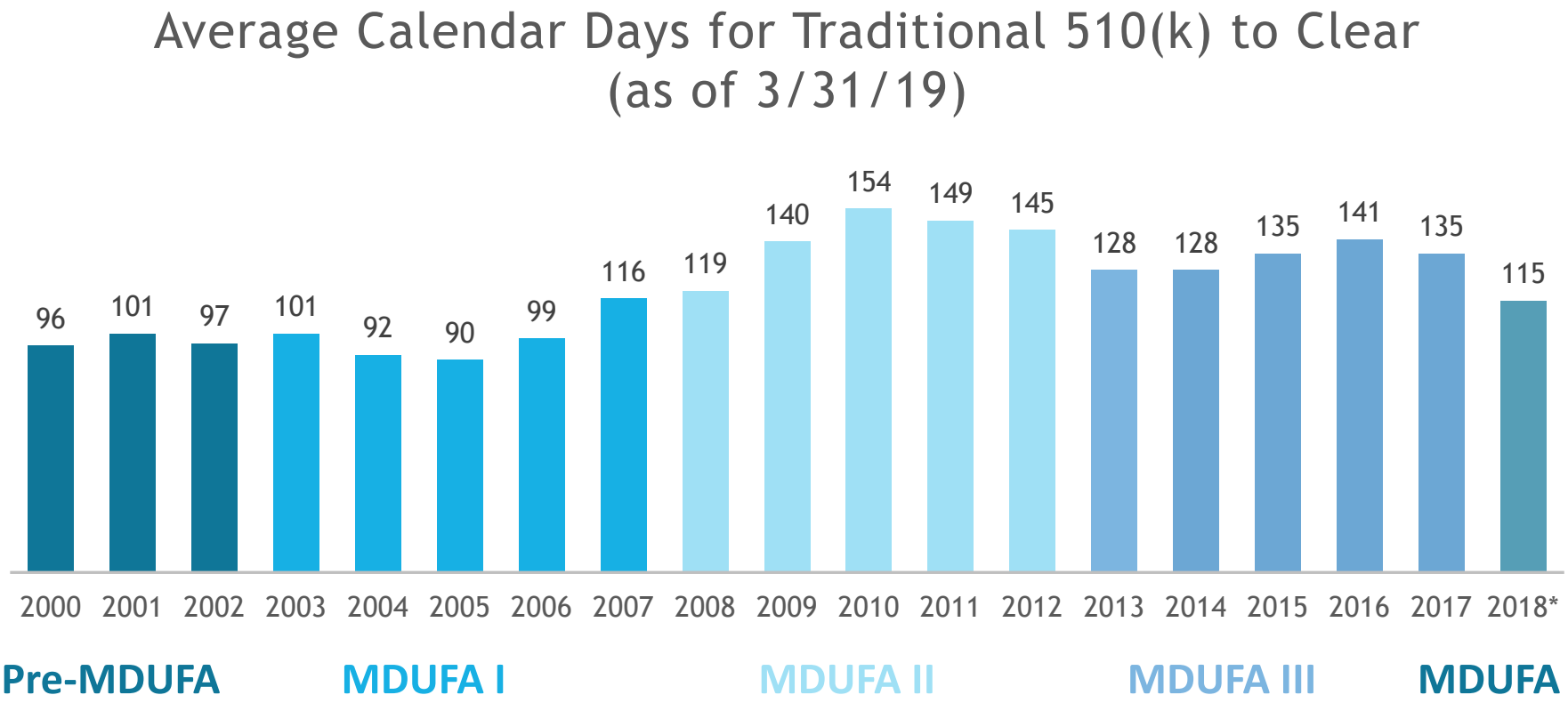
Understand the 510(k) review process



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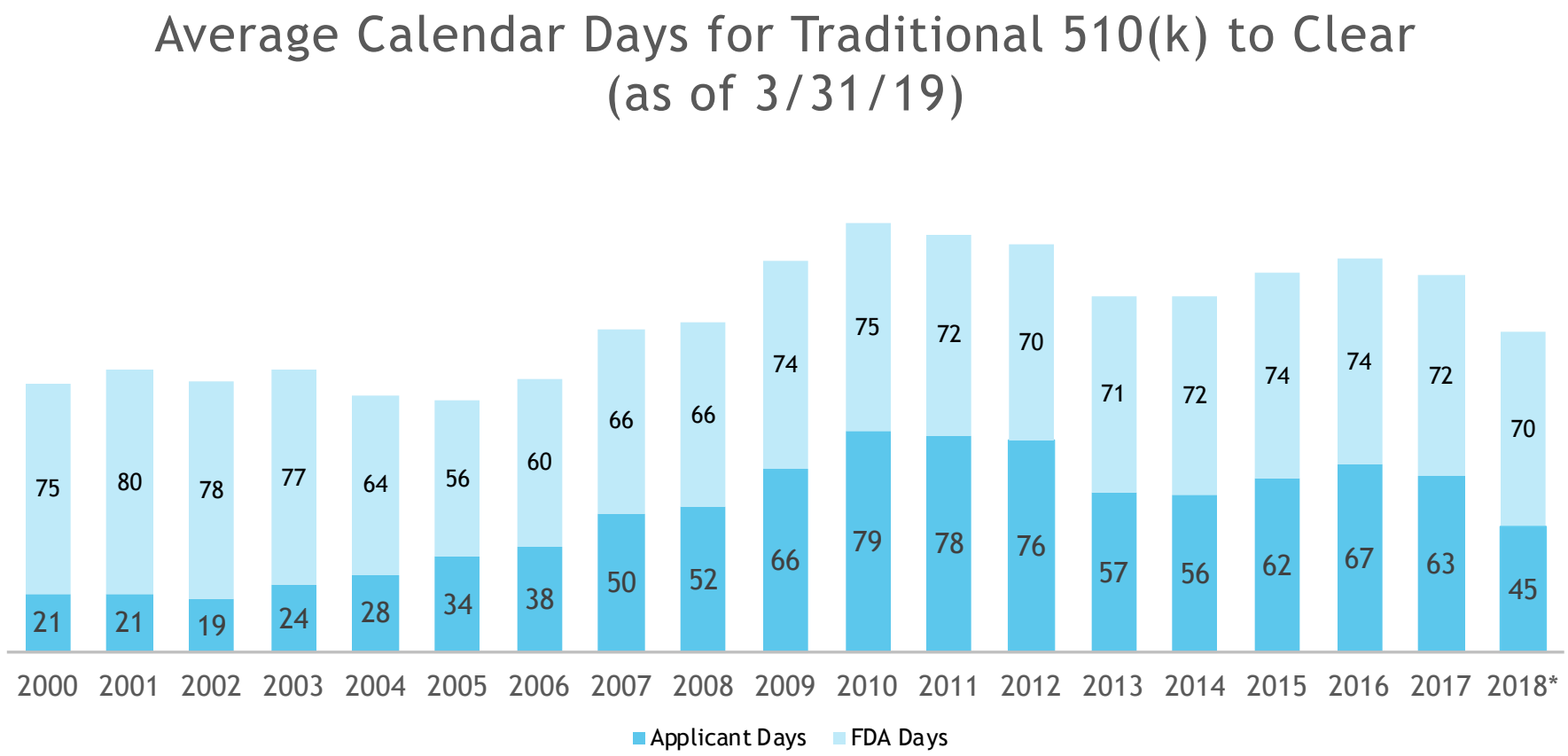


https://www.fda.gov/media/128160/download

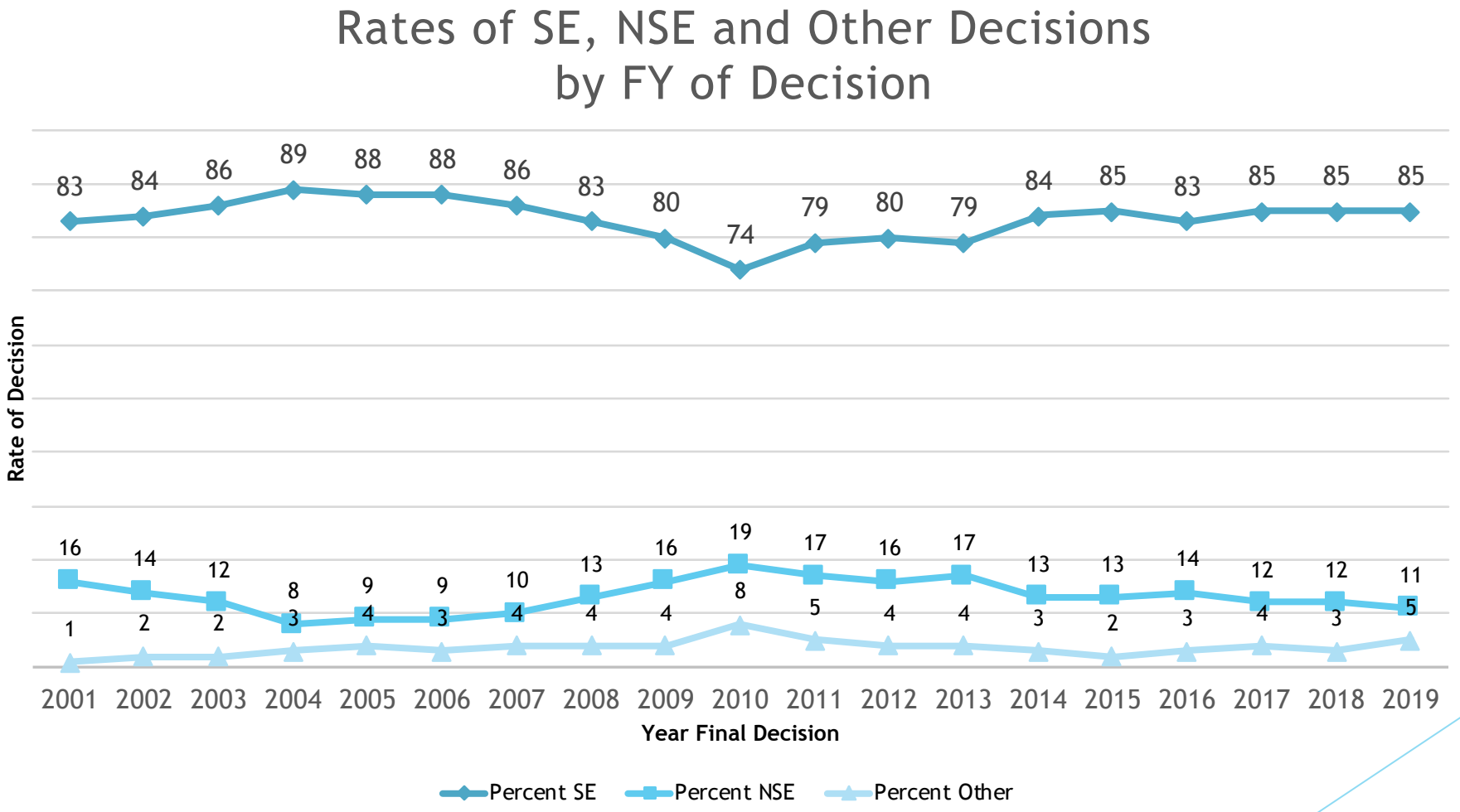
Understand the 510(k) review process

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

Understand the 510(k) review process



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?

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