Mapping Your Way Through the FDA's 510(k)

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National Cancer Institute – Small Business Innovation Research

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

NIH SEED

Welcome

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- Now
  - NIH Office of Extramural Research
    - SEED (Small Business Education & Entrepreneurial Development)
  - MITRE Corporation
    - Operating Federally Funded Research & Development Centers (FFRDC)
    - Not-for-Profit
- Before
  - FDA Center for Devices & Radiological Health (CDRH)
    - Division of Radiological Health
    - Division of Imaging Diagnostics & Software Reliability

NIH SEED (Small Business Education & Entrepreneurial Development)

- The Innovator Support Team serves NIH innovators and program officers
- Led by Dr. Chris Sasiela, the team is comprised of interdisciplinary scientists and entrepreneurs

- Manufacturing, reimbursement, intellectual property, partnerships, investments, **regulatory pathways**, …
- Information and resources for commercialization of innovative medical products
- Venture capitalists, technology transfer organizations, angel investors, strategic partners

NIH SEED – Innovator Support Team
Example Services

Consultation for commercialization challenges

- Dry runs for FDA meetings
- Pitch coaching

Guidance for academic innovation hubs

- NIH Centers for Accelerated Innovations
- Research Evaluation & Commercialization Hubs

Contact your small business program officer (link) to connect with us!

Goal:
A basic understanding of 510(k) process for our panel discussion

- There are exceptions to much of the information that follows

510(K) PREMARKET NOTIFICATIONS

National Institutes of Health
Office of Extramural Research

Disclaimer:
The content is developed by NIH SEED based on its collective experience working with the NIH innovator community. This information has been developed, for informational purposes, to address questions frequently asked by NIH awardees, and represents the experiences of the subject matter experts who contributed to its development.

Premarket Review at CDRH

For established device-types

Class	Risk	Review Pathway
III	High	Premarket "Approval" (**PMA**)
II	**Medium**	**510(k) "Clearance"**
I	Low	No Premarket Review

For first-of-their-kind device-types:

- PMA by default
- **De Novo** "granted" to pave the way for future 510(k)
  - Only an option if risk/benefit is controllable/suitable

For reference, in April + May 2020:

7 PMA (original)
5 De Novo
493 510(k)

Summaries are available on CDRH public databases

510(k) – Key Terms and Concepts

1. Predicate
   - Existing device, already has 510(k) clearance (or De Novo)
   - Same device-type (regulation/classification) as yours
2. Intended Use
   - The general purpose of the device. Exactly what is it meant to do?
3. Substantial Equivalence (SE)
   - Same **intended use** as the **predicate**
   - And where there are technical differences...
     data shows your device is as safe & effective as the **predicate**

- FDA will decide based on your 510(k) if the device is SE

Intended Use and Indications For Use

- Intended Use
  - The general purpose of the device. Exactly what is it meant to do?
  - 510(k): Must be the **same as the predicate**
- Indications For Use (IFU)
  - The conditions or reason or situation for someone to use the device.
  - 510(k): Does not need to be identical to the predicate
    - But should not raise new questions safety or effectiveness

Name that device!

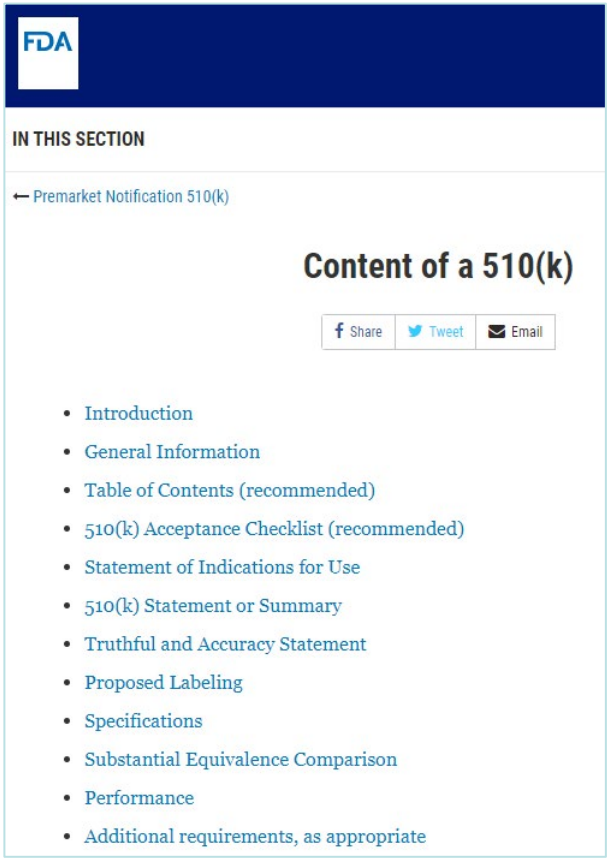
Intended use	Indications for use
Make images of internal structures of the body	Images are derived from nuclear magnetic resonance properties. Additional contrast agents may be used. When interpreted by trained physician, can be yield information to aid in diagnosis

Your 510(k) Submission

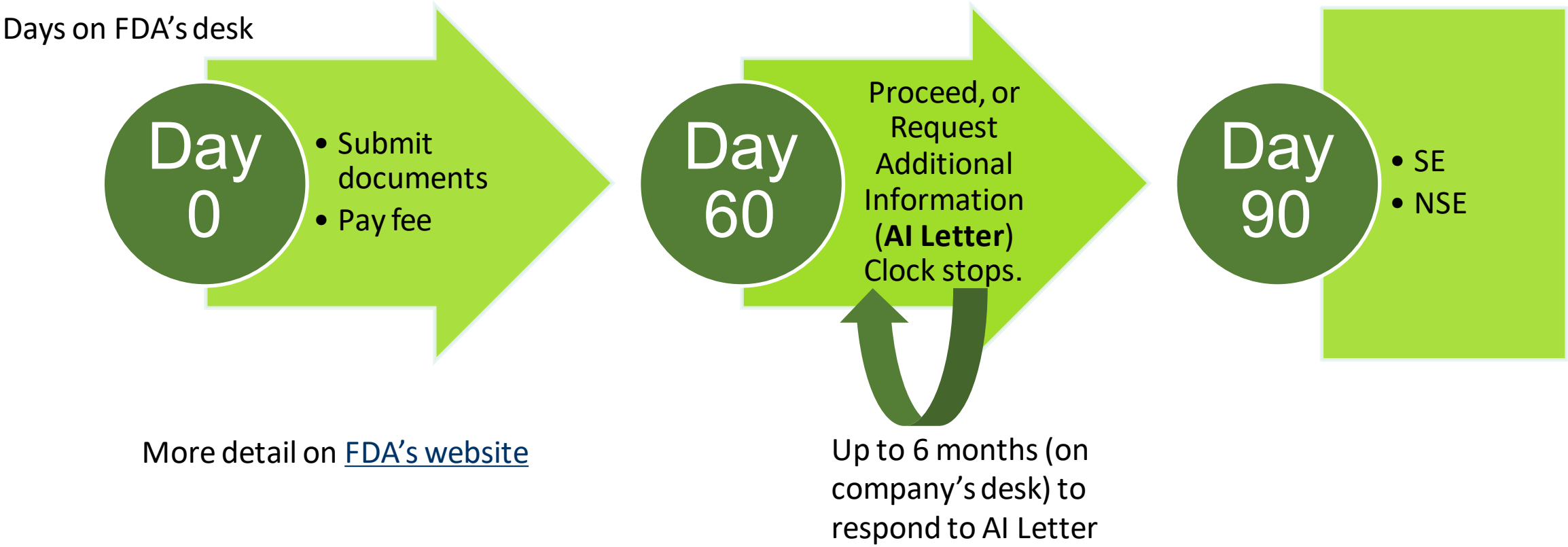
- Your 510(k) is your argument to FDA that your device is substantially equivalent to a specific predicate

- The argument will be supported by:
  - Technical/clinical description of device
  - Detailed comparison of similarities and differences to predicate
  - Performance data
  - Draft labeling
    - User manual
    - Promotional language
  - Any other documents to make your case!

- Expected content is detailed on FDA's website

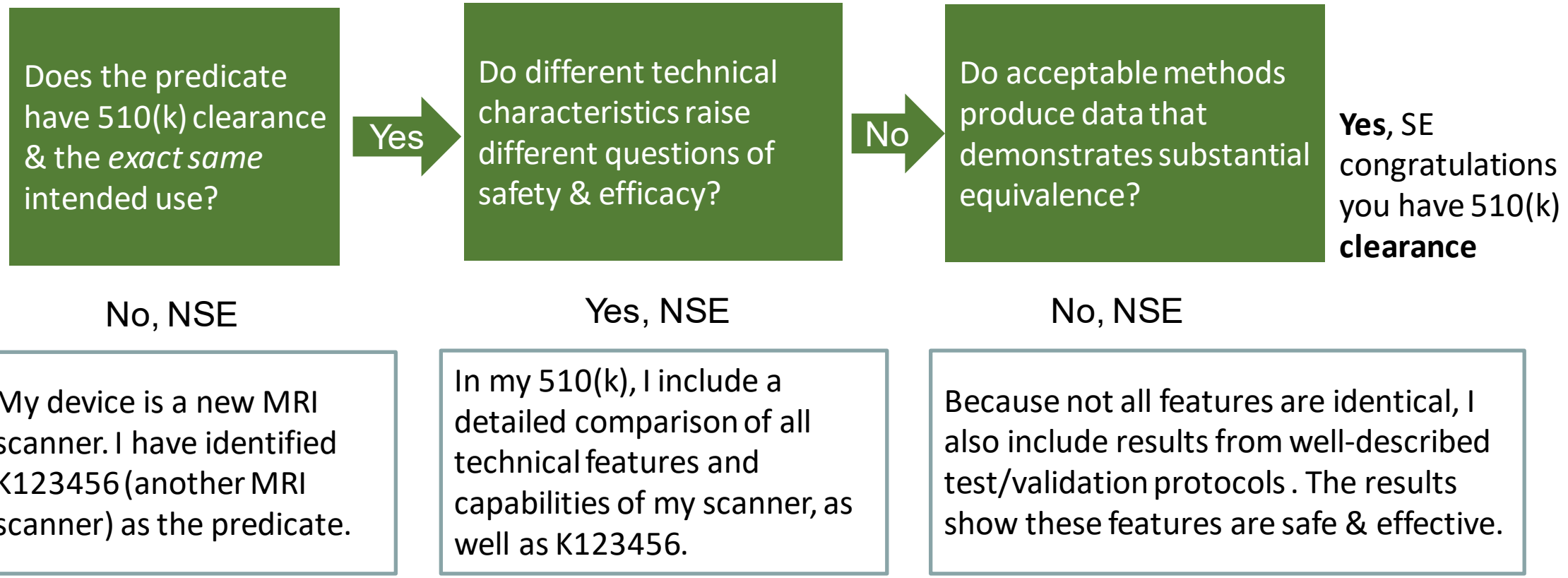


The Review Timeline



More detail on [FDA's website]

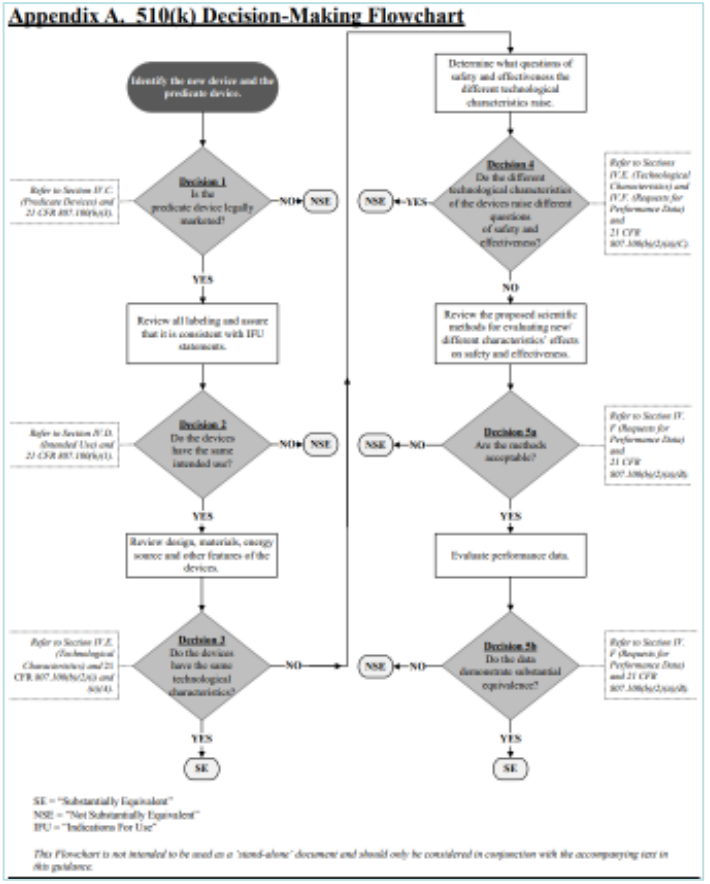
The 510(k) Flowchart - Abridged



Review the FDA guidance for more steps, details, and examples

Starting Points

- Become familiar with 510(k) early on in development
  - Use the public database to read 510(k) summaries of potential predicates
    - What standards did they use?
    - What performance data did they include?
    - Which CDRH office reviewed it?
    - Start to compare and contrast (goal: SE)
  - Read the FDA 510(k) guidance, and navigate the actual flowchart
- Confirm that 510(k) is applicable
  - Request a pre-submission meeting with FDA
    - Free, common, best before your first submission!
  - New technology may yield new policy
    - For example, Digital Health and clinical decision support



Types of 510(k)

Traditional 510(k)

- As described above (the default)
- Most common

Abbreviated 510(k)

- Relies **entirely** on established and accepted test methods

Special 510(k)

- When making minor changes to **<u>your</u> existing cleared device**
- Has a 30-day timeline

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