Demystifying Medical Devices: FDA Overview

Presented by: Iris Sherman

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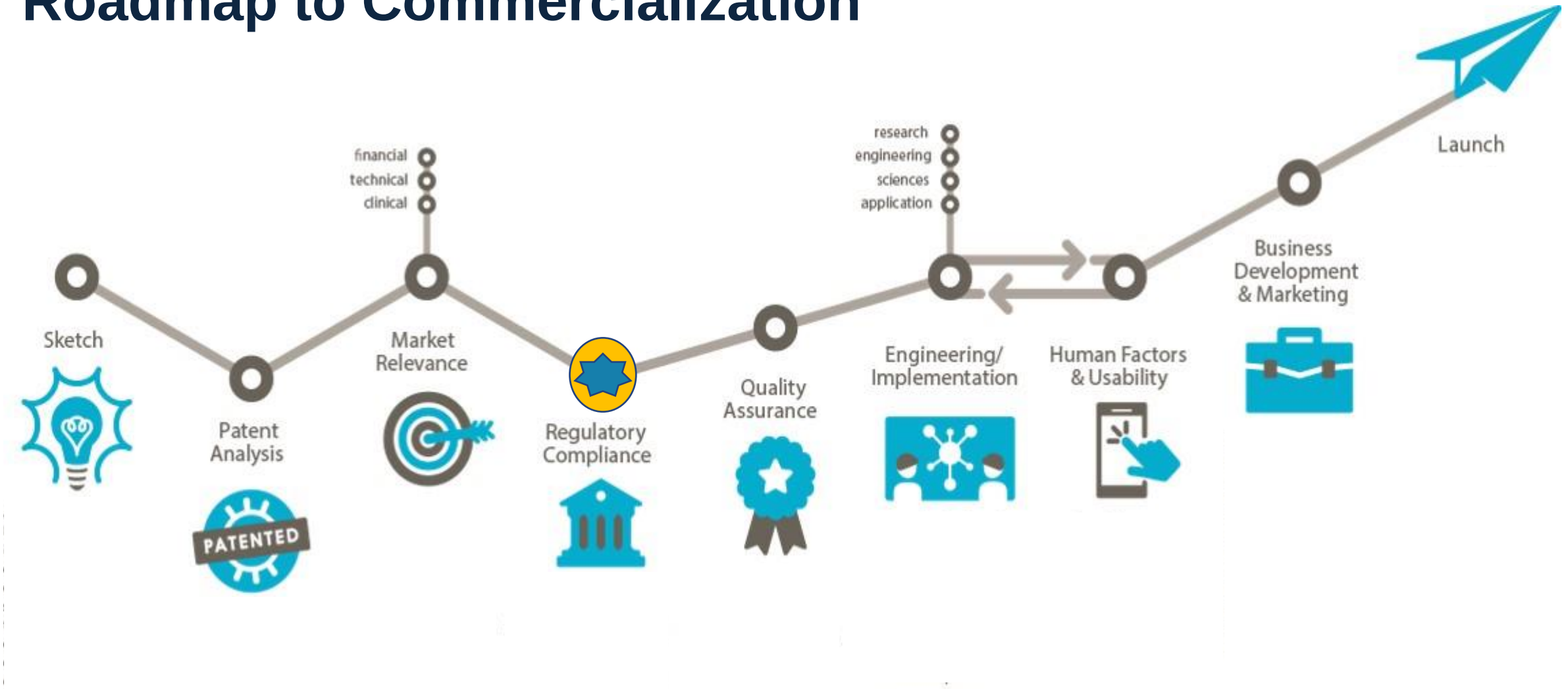
Roadmap to Commercialization



https://starfishmedical.com/blog/sketch-to-launch-commercialization-process/

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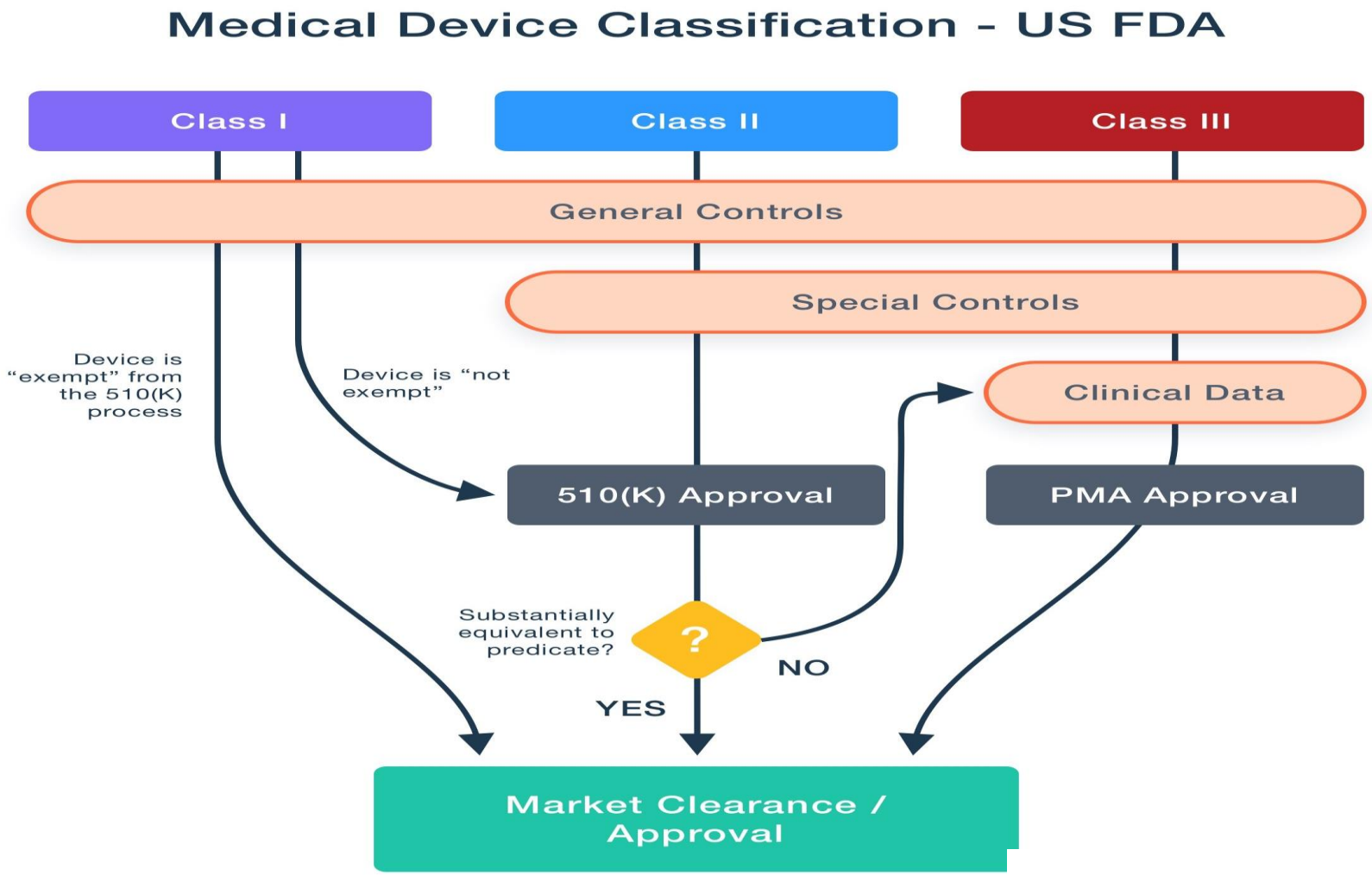
Roadmap to Regulatory Compliance



FDA Regulatory Requirements on Medical Devices

Posted by Sierra Labs on Jul 16, 2019
https://blog.sierralabs.com/iso-13485-regulatory-requirements-on-medical-devices

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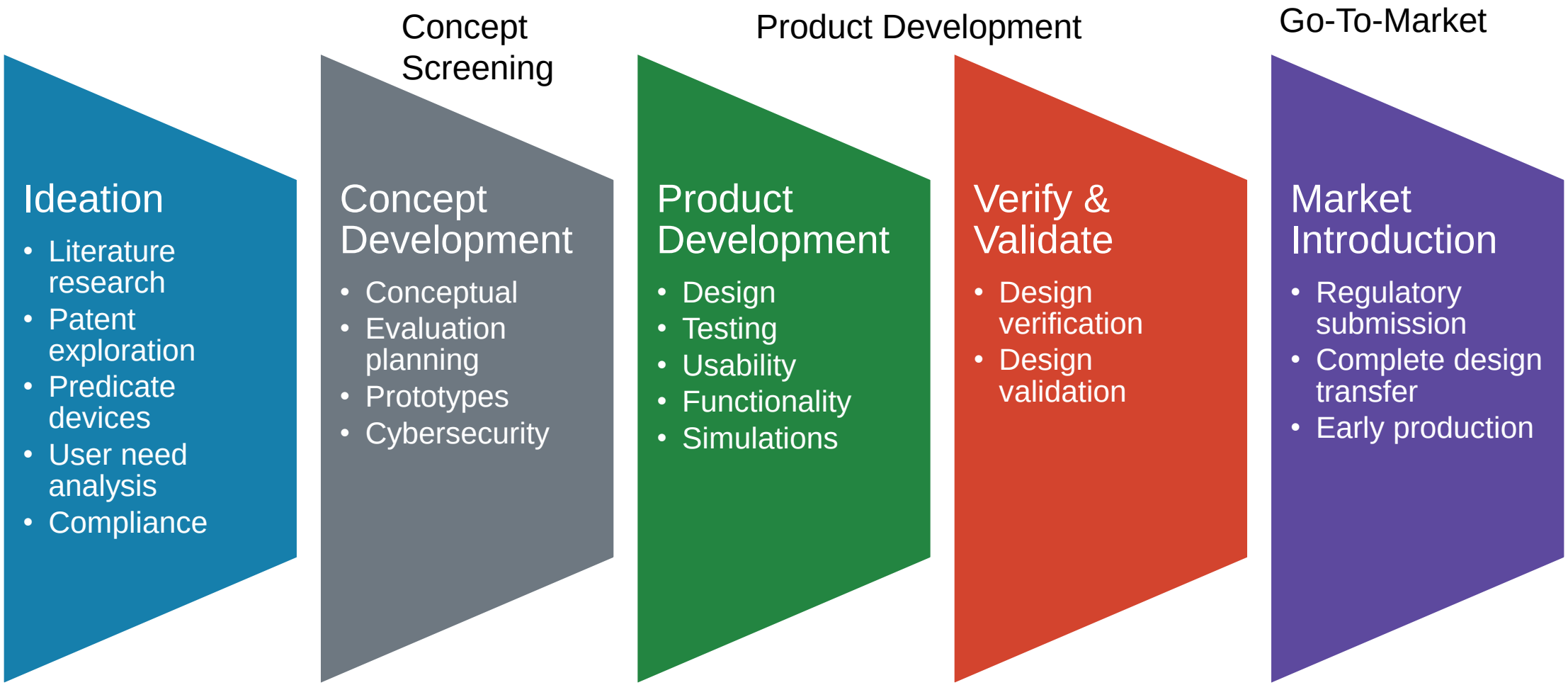
Roadmap to Medical Device Design and Development



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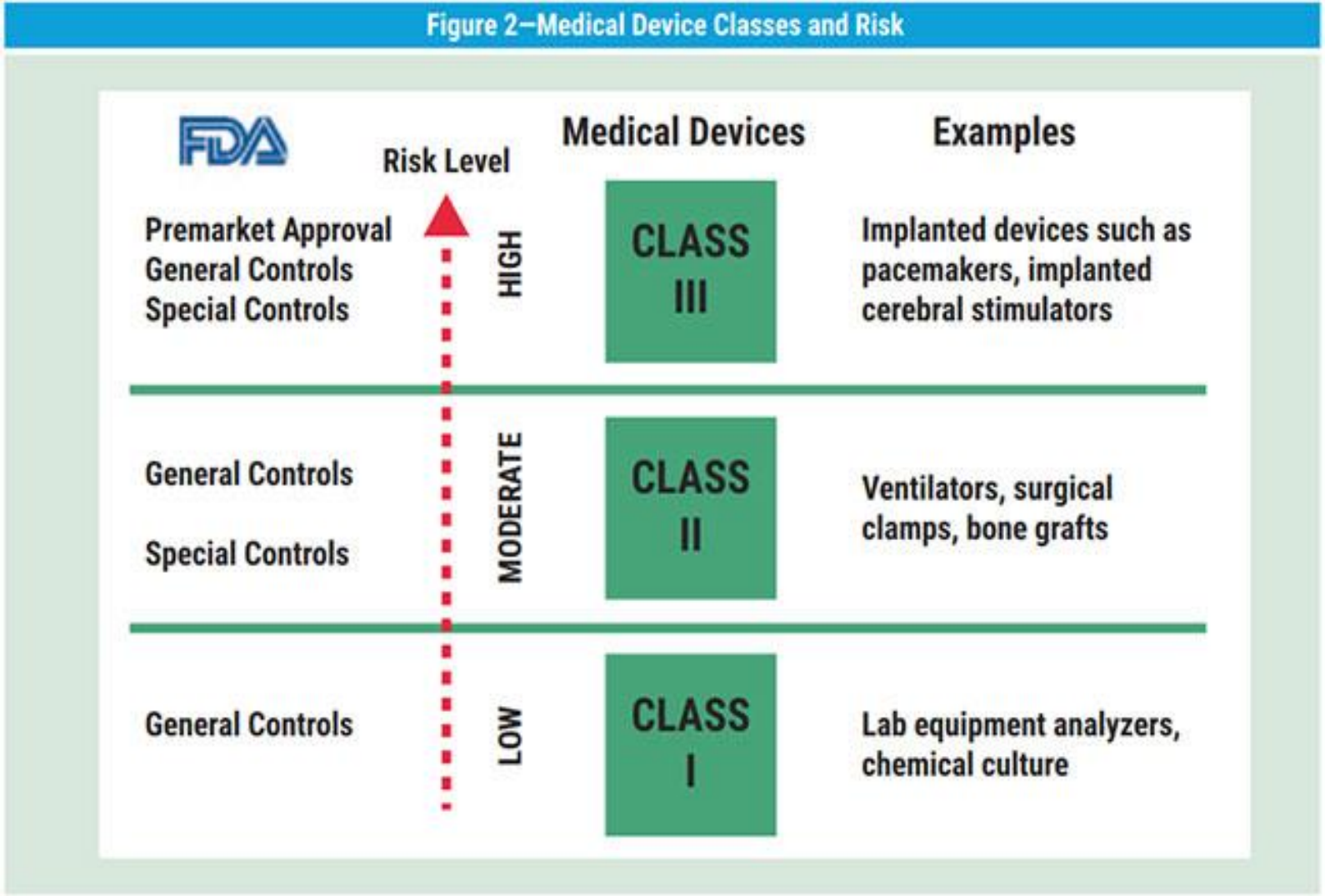
How to Classify Medical Devices

- Evaluate the risk of your device to determine the class and applicable regulatory controls
- Familiarize yourself with different classification determination methods



https://www.isaca.org/resources/isaca-journal/issues/2019/volume-4/the-internet-of-medical-things-anticipating-the-risk

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Classification Determination Methods

U.S. FOOD & DRUG ADMINISTRATION

Search for Appropriate Classification

- Product Classification Database:
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
- Search for FDA product codes
- Most common method

Search for Clearances or Approvals

- 510(k) Clearance Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Premarket Approval (PMA) Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- De Novo Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

Search for Predicates

- All establishments currently marketing a medical device must be registered and list their devices
- Establishment Registration and Device Listing Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

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Submission Types

510(k) ~ *is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act).*

PMA ~ *is the most stringent type of device marketing application required by FDA and typically Class III. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).*

DeNovo ~ *this classification is appropriate for devices that have not been classified under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act. These devices do not fit into any particular class, have no equivalent device that is currently marketed, or have not been determined to be substantially equivalent as the result of a 510(k) application.*

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De Novo Basics

Medical devices that are new or novel, and thus not substantially equivalent to a previously cleared or pre-amendments device, are automatically classified as Class III—which would require FDA approval of a pre-market approval application (PMA).

The De Novo classification process allows medical device manufacturers to submit a De Novo request to FDA to obtain a Class I or Class II classification. Upon receipt, FDA beings an acceptance review for administrative completeness before a substantive review is performed.

FDA may Refuse To Accept (RTA) the application or delay the process if the submission is not administratively complete. This is a crucial step in the De Novo classification request process.

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How to Search for Predicate Device

- Names of similar devices - traded name under which the device is marketed;
- Manufacturer(s) of the similar device(s);
- Marketing status, i.e., pre-amendments or post-amendments device;
- 510(k) numbers for post-amendments devices;
- Classification information, i.e., product codes, classifying regulations, etc., for your device.

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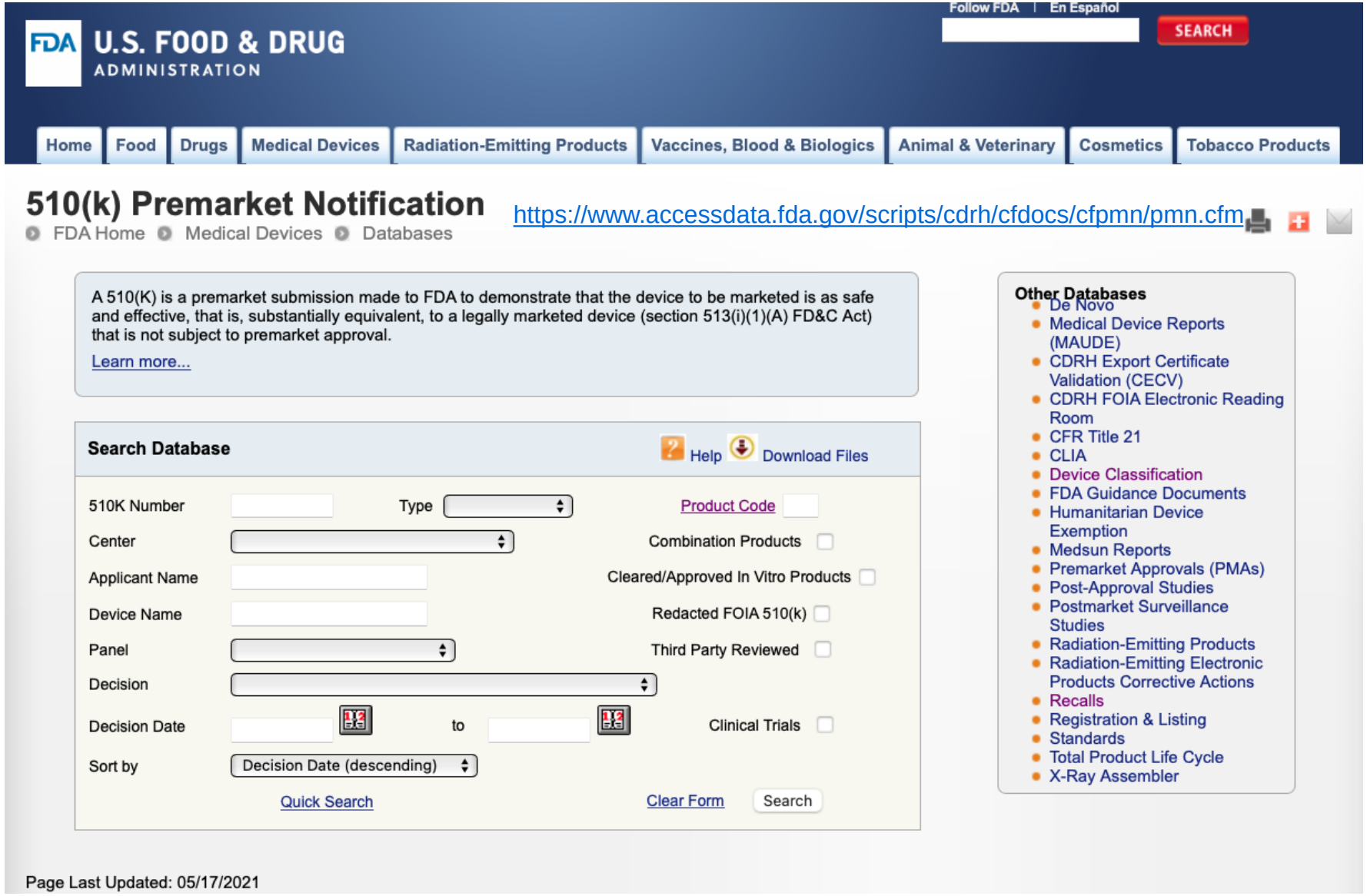
How to Search for Predicate Device



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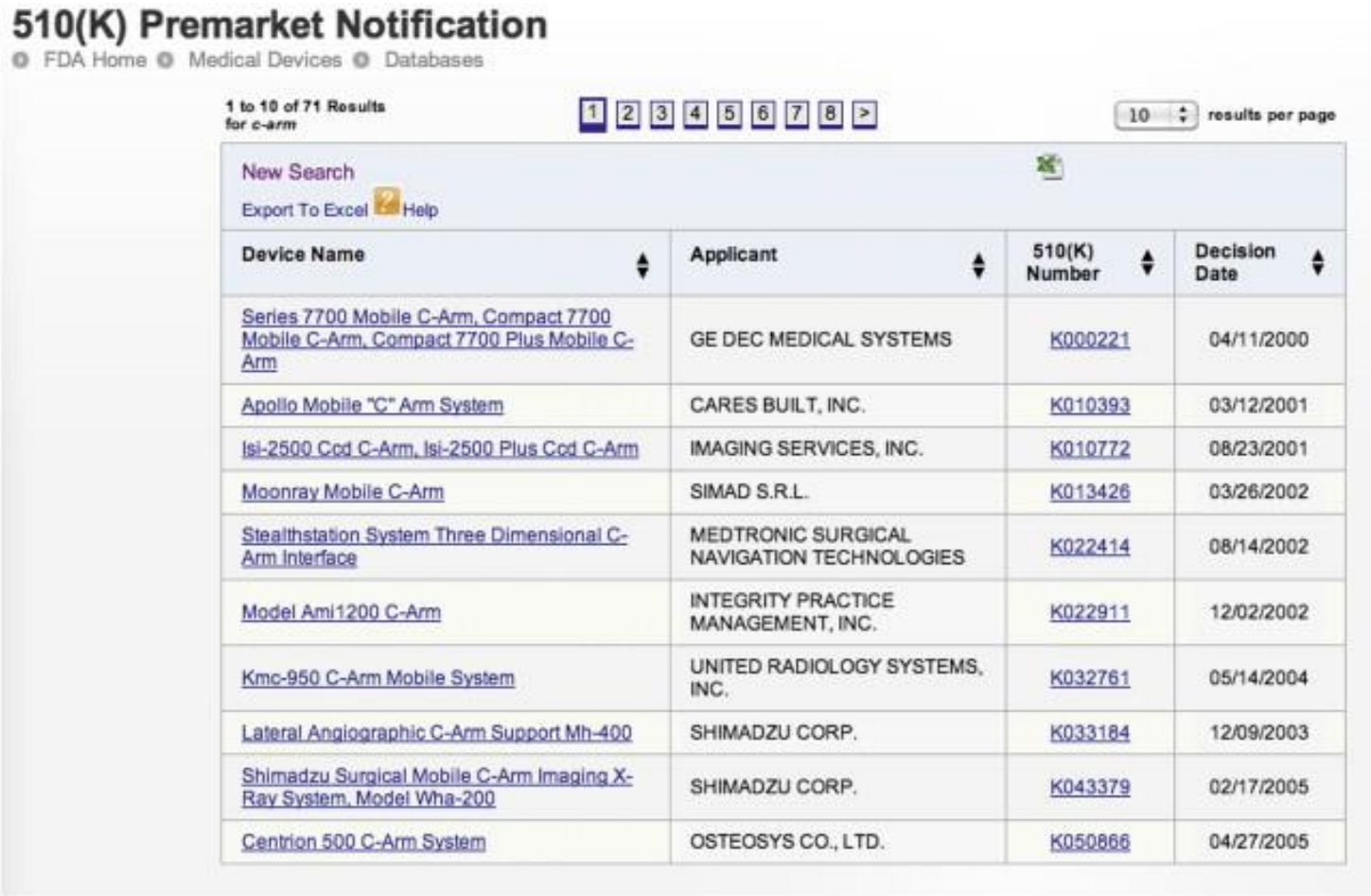
How to Search for Predicate Device



510(K) Premarket Notification

FDA Home • Medical Devices • Databases

1 to 10 of 71 Results for *c-arm*

1 2 3 4 5 6 7 8 >

10 results per page

New Search

Export To Excel Help

Device Name	Applicant	510(K) Number	Decision Date
Series 7700 Mobile C-Arm, Compact 7700 Mobile C-Arm, Compact 7700 Plus Mobile C-Arm	GE DEC MEDICAL SYSTEMS	K000221	04/11/2000
Apollo Mobile "C" Arm System	CARES BUILT, INC.	K010393	03/12/2001
Isi-2500 Ccd C-Arm, Isi-2500 Plus Ccd C-Arm	IMAGING SERVICES, INC.	K010772	08/23/2001
Moonray Mobile C-Arm	SIMAD S.R.L.	K013426	03/26/2002
Stealthstation System Three Dimensional C-Arm Interface	MEDTRONIC SURGICAL NAVIGATION TECHNOLOGIES	K022414	08/14/2002
Model Ami1200 C-Arm	INTEGRITY PRACTICE MANAGEMENT, INC.	K022911	12/02/2002
Kmc-950 C-Arm Mobile System	UNITED RADIOLOGY SYSTEMS, INC.	K032761	05/14/2004
Lateral Angiographic C-Arm Support Mh-400	SHIMADZU CORP.	K033184	12/09/2003
Shimadzu Surgical Mobile C-Arm Imaging X-Ray System, Model Wha-200	SHIMADZU CORP.	K043379	02/17/2005
Centrion 500 C-Arm System	OSTEOSYS CO., LTD.	K050866	04/27/2005

You can **search the releasable 510(k) database** by Panel, 510(k) number, Product code or Device name. A search query will produce information from the database in the following format:
Device Classification Name:
Regulation Number:
510(k) Number:
Device Name:
Applicant:
Contact:
Product Code:

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Publicly Available Documents

K061451 p. 1/1

510(k) SUMMARY

AUG 11 2006

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, C-100
Austin, TX 78754-3832

510(k) CONTACT: Glen Neally
Ph: (512) 836-5001

TRADE NAME: Ascension® CMC

COMMON NAME: prosthesis, wrist, carpal trapezium

CLASSIFICATION: 21 CFR §888.3770 Wrist joint carpal trapezium polymer prosthesis

PRODUCT CODE: KYI

PANEL: Orthopedic Devices

PREDICATE DEVICE: Ascension® PHS, (K041451)

DEVICE DESCRIPTION:
The Ascension® CMC is intended for use as a hemi joint replacement for the base of the first metacarpal of the carpometacarpal (CMC) joint. The Ascension CMC is a one component prosthesis having a saddle configuration articular surface which bears against the mating saddle articular surface of the trapezium. The saddle design allows for flexion-extension joint motion and abduction-adduction motion. It is designed to be a press fit device. Each device is comprised of a pyrocarbon layer encasing a machined graphite substrate. The graphite substrate material is impregnated with a small amount (1 atomic percent) of tungsten. This small amount of tungsten renders the graphite substrate radiopaque. The device is provided sterile in packaging containing a single device.

INTENDED USE:
The Ascension® CMC is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion. This is an uncemented prosthesis designed for press fit use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests conducted on Ascension CMC devices, in vitro material biocompatibility tests, and pre-clinical animal tests demonstrate that the Ascension CMC is substantially equivalent to the predicate device.

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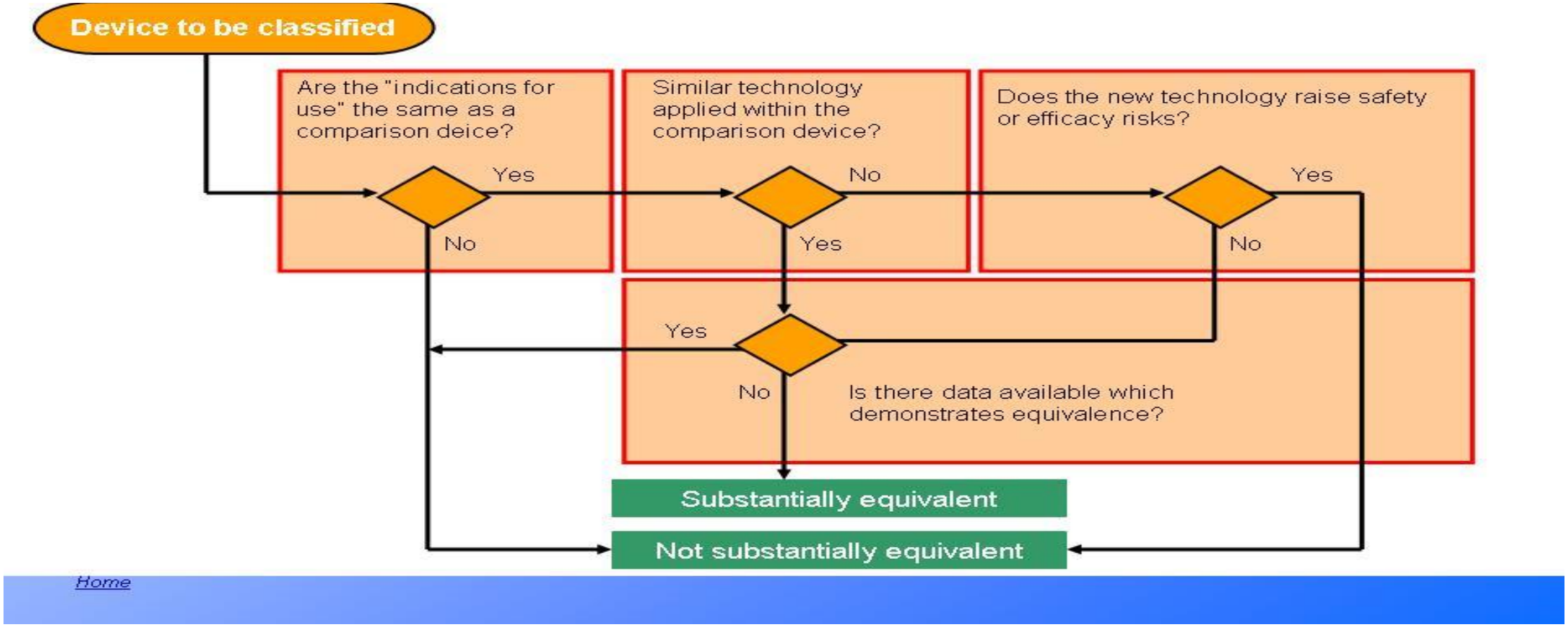
510(k) Predicate Device Determination



https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices

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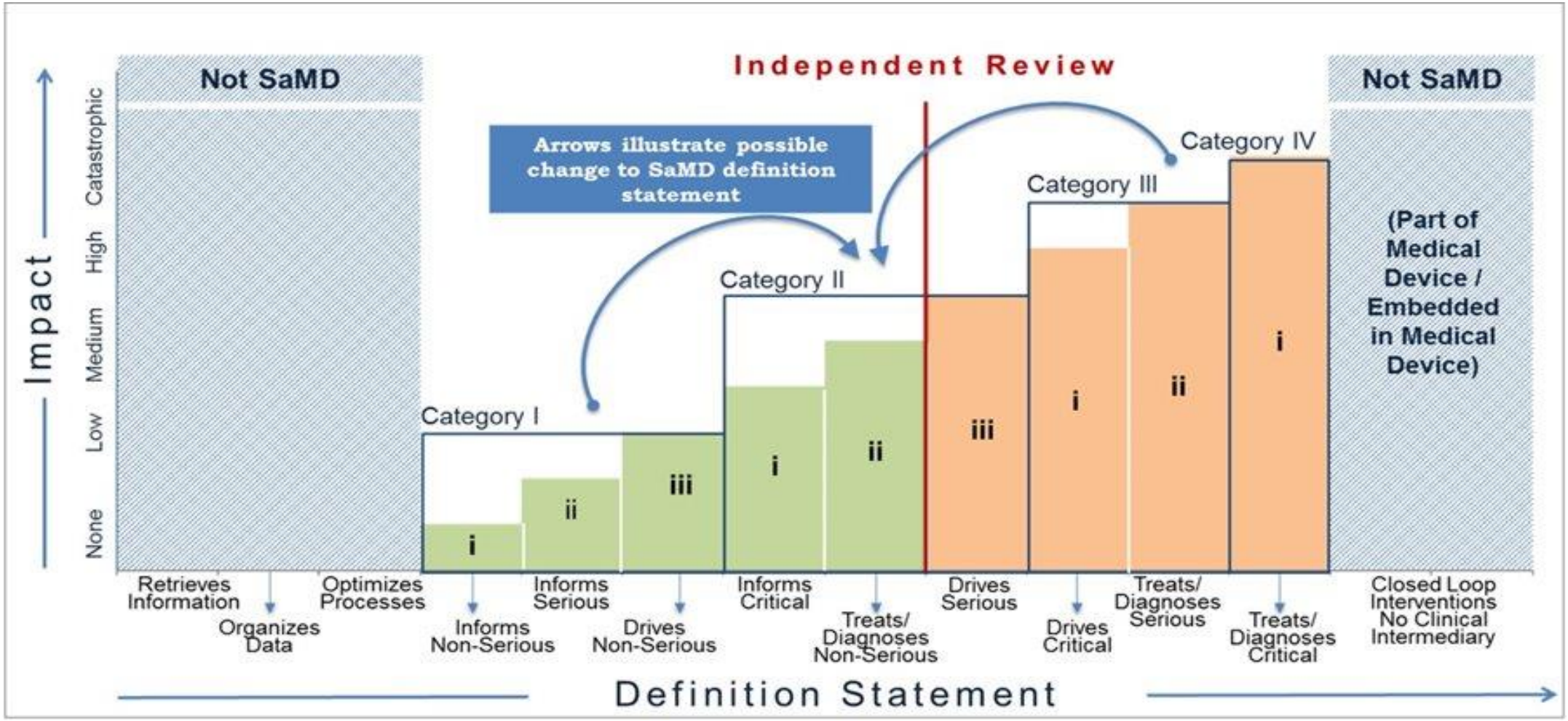
Is Your Software A Medical Device?



https://www.raps.org/news-and-articles/news-articles/2019/3/is-your-software-a-medical-device

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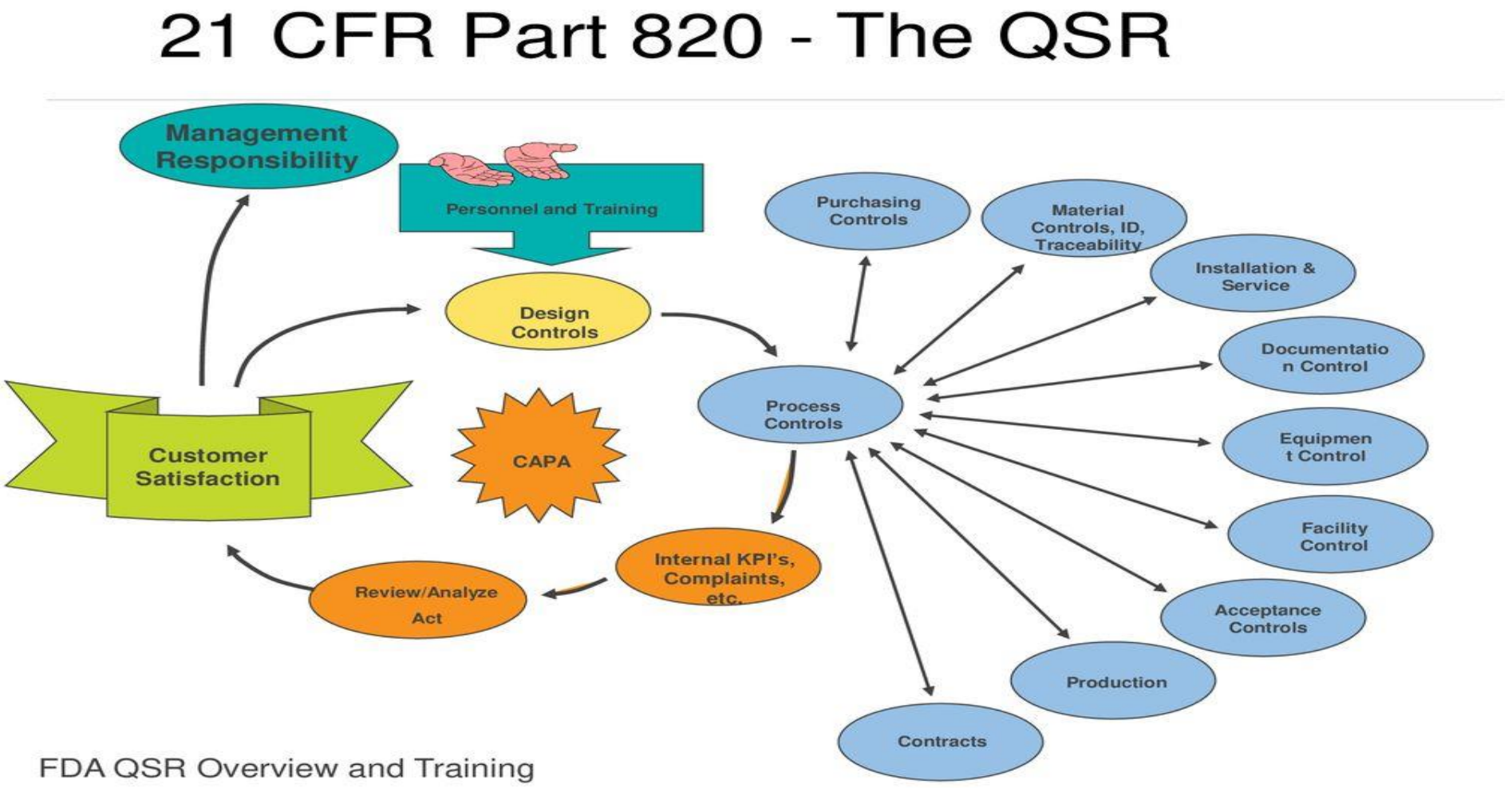
Don’t Forget the Documentation



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Components of a 510(k)

A Practical Guide to Class IIa Medical Device Development; May 2020, Applied Sciences 10(10):3638

ER #	Scope
Part I – General Requirements	
1	Risk Reduction & Acceptable Risk/Benefit
2	Safety and Risk Controls
3	Intended Performances
4	Lifetime of the Device
5	Transportation & Storage
6	Side-effects must Constitute Acceptable Risk
6a	Clinical Evaluation
Part II – Design & Construction Requirements	
7	Chemical, Physical &Biological Properties
8	Infection & Microbial Contamination
9	Construction & Environmental Properties
10	Device with a Measuring Function
11	Protection Against Radiation
12	Devices with an Energy Source
13	Information Supplied by the Manufacturer

	ITEM
1.	Device Description
2.	Indications for Use
3.	Comparison to Predicate
4.	Summary of Supporting Data
5.	Clinical Context of Use
6.	Relevant Devices Guidance
7.	Mechanism of Action
8.	Engineering drawings/Illustrations
9.	Proposed Labeling
10.	Sterilization and Shelf Life
11.	Electrical Safety
12.	Benchtop Performance Testing
13.	Animal Performance Testing
14.	Clinical Performance Testing

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510(k) Submission Process

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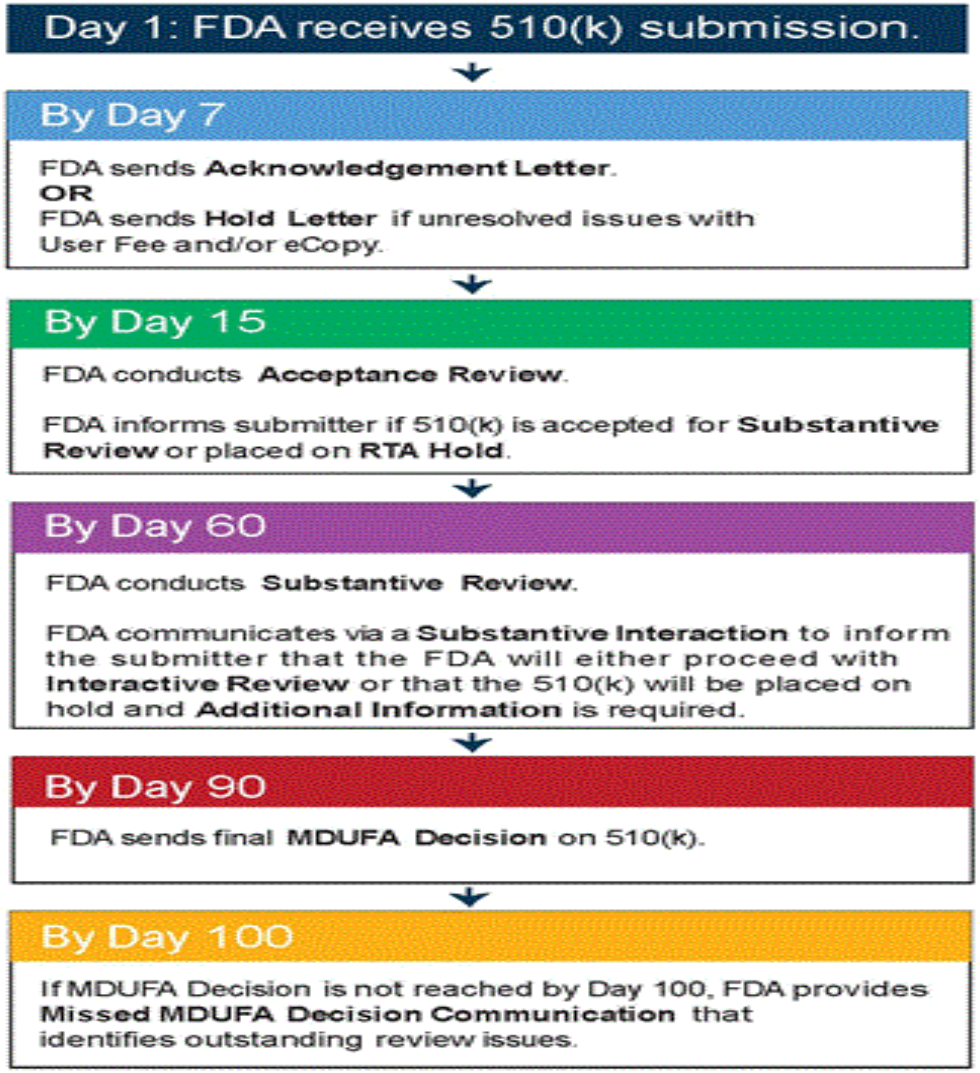
- **Log-in and Acknowledgement Procedure**
  - eCopy Program for Medical Device Submissions webpage
  - The proper user fee payment was received for the submission.
  - A valid eCopy of the 510(k) submission was provided



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Informational Meetings with FDA for Feedback

Q-Sub Type: (Q-Submissions)

A meeting with the intent to share information with FDA without the expectation of receiving feedback

FDA is in listening mode

Timeframe: 90 days, resource permitting

An Informational Meeting may be appropriate:

- Provide an overview of ongoing device development
- Familiarize reviewers about new device with significant

Differences in technology from currently available devices

A formal written request for feedback is required

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Examples of Appropriate Questions to the FDA

Are the proposed trial design and selected control group appropriate?

Does the FDA concur with the use of the proposed alternative test method, which is different than the normally recognized standard?

Is a “moderate level of concern” the appropriate level of concern for my software?

Are there concerns with the predicate device proposed?

What specific information about a post approval study should the PMA contain?

Are the proposed study designs for demonstrating precision and accuracy adequate to support use of the assay in the Phase 3 clinical study?

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Top 10 things you can do to speed along your 510(k), PMA, or De Novo submission

1. Don’t guess. When in doubt, ask the FDA. Consider a pre-sub or 513(g) Request for Information. Proactive FDA interaction will save you time down the road.
2. Know the FDA guidance(s) applicable to your device and submission pathway.
3. Engage an expert to compile and/or review your submission. Writing for the FDA requires a unique skill set.
4. Do not promote your investigational device before it is approved—this is not allowed per 21 CFR 812.7. Reviewers often visit company websites to learn about a company and its device.
5. Adequately budget the regulatory roadmap.
6. Establish reasonable timelines to clearance or approval.
7. Don’t set out on the 510(k) pathway when your device belongs on the De Novo or PMA pathway. The path to clearance or approval is littered with companies that have chosen the wrong pathway and gone bankrupt as a result.
8. Get it right the first time. Mistakes will affect your FDA review.
9. Consider whether a pre-submission meeting is necessary.
10. Work collaboratively with the FDA.

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Resources

Cited Resource	URL
How to Classify Your Medical Device	https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
Regulatory Controls	https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls
Class I/II Exemptions	https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions
Premarket Notification 510(k)	https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
Premarket Approval	https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma
510(k) Clearance Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
Premarket Approval (PMA) Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
Establishment Registration and Device Listing	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
De Novo Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff
FDAand Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
Cybersecurity Toolkit for Digital Health	https://massdigitalhealth.org/industry-resources/cybersecurity-toolkit

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