Regulatory Strategy

Guide Overview

Objectives

- Research predicate devices
- Determine and verify target device classification
- Develop regulatory strategy for FDA clearance

Outcomes

- Go-no-go decision for preparing a FDA submission
- Timeline for FDA Submission and anticipated clearance
- Written Regulatory Plan

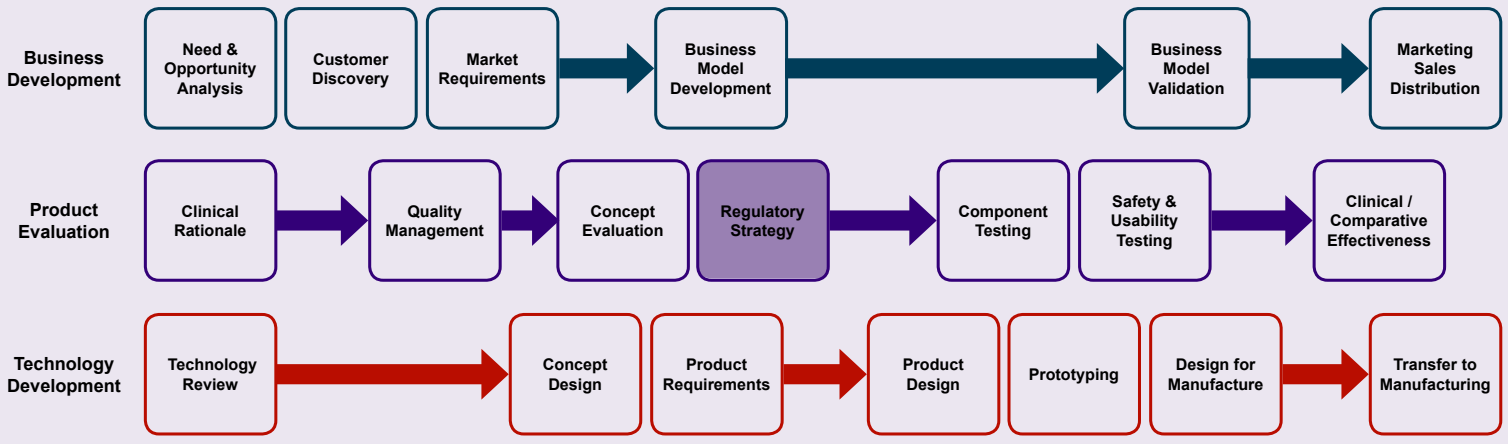
Next Steps

- Communicate with FDA and prepare for a formal FDA submission
- Identify any additional bench top/clinical test that may need to be completed

Relevant Resources

- FDA CDRH Database
- FDA Device -- Not a Device Instructions
- FDA Device Classification Panels
- FDA 510(k) Database
- FDA Registration & Device Listing Database
- e-CFR
- Who Must Register List and Pay the Fee?
- FDA Medical Device Exemptions
- **Regulatory Strategy Supplemental Reading**
- **Regulatory Strategy Worksheets**
- **Regulatory Plan Worksheet**

Commercialization Methodology



The Center for the Translation of Rehabilitation Engineering Advances and Technology

TREAT is part of the National Institutes of Health (NIH) Medical Rehabilitation Research Resource Network (MR3). Funding is provided by the National Center for Medical Rehabilitation Research (NCMRR) in the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) through awards R24HD065703 and P2CHD086841.

10 Water Street, Suite 410
Lebanon, NH 03766
T: (603) 448-2367
F: (603) 448-0380
info@treatcenter.org

INDICATIONS FOR USE (IFU)

Answer and record the following questions on IFU Worksheet:

- How the device is intended to be used – specify purpose for which the safety and effectiveness of the device has been validated. (Ex. screening, real-time monitoring, treatment, etc.)
- For whom the device is intended to be used – specify intended population (age, patient group, condition(s))
- Setting or environment of intended use (ex. in home, under supervision of a trained health care professional, etc.)
- Are there populations that should not use the device, or potential differences in diversity, growth or development milestones (contradictions).
- Other information that may be included in the IFU:
  - Information the device reports
  - Organ or body system(s) examined or impacted (ex. brain, heart, etc)
  - Conditions under which the device will be used
  - Who will use the device (operator or target user)? For what condition?
  - Therapeutic implications from device results
  - Is the device proposed for prescription or over-the-counter use?
  - Could the device qualify for expedited review or humanitarian use designation?

DEVICE OR NOT A DEVICE?

1. According to the FDA, a device is defined as:

   "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

   1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

   2. 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

   3. 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 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 its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)."
2. An important point to keep in mind is that the FDA is looking at the safety of use (are there risks associated with the device), along with the effectiveness in the claims you are making.
3. Search the Center for Devices Radiological Health (CDRH) Database for similar devices by using parts of the name, function or medical description. This will give an idea of whether it is a device; or if it meets the definition of a device, but there are no similar devices in CDRH, it could be considered De Novo.

   NOTE: More information on De Novo can be found in the Regulatory Strategy Supplemental Reading
4. Look through Step 2 in FDA's Device -- Not a Device Instructions for further information.

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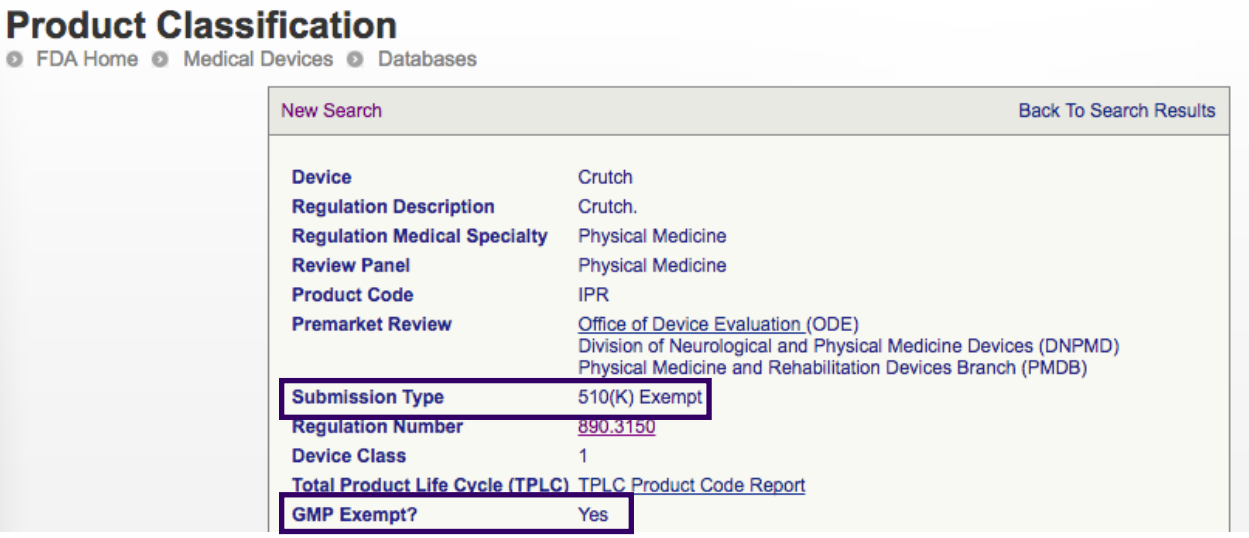

Product Classification

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Device	Crutch
Regulation Description	Crutch.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	IPR
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(K) Exempt
Regulation Number	890.3150
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Figure 1: Example search of the FDA CDRH Database for a crutch showing 510(k) and GMP exemptions.

DEVICE CLASSIFICATION

1. Go back to the CDRH Database and type in a description of the device. Search for an applicable regulation number. If there is not a regulation number, then begin to look for parts of the name and function, or reference Predicate Device Search Worksheet if this is complete

   NOTE: If the device panel/medical specialty is known, go directly to the FDA Device Classification Panels.

   NOTE: **Predicate Device** – *a substantially equivalent device that has already been proven safe and effective by gaining FDA clearance. A device legally marketed by a Premarket Approval (PMA) cannot be considered a predicate device.*

2. Determine if the most suitable predicate device is Class I, Class II or Class III and refer to the appropriate section below:

CLASS I DEVICE:

1. Once a suitable device(s) is found, if Class I, note whether the device is 510(k) exempt and/or Good Manufacturing Practices (GMP) exempt as seen in the highlighted boxes below:
2. Alternatively, if it is already known this is likely a Class I device, search the FDA Medical Device Exemptions web page to find the specifications for this device.

   Example: Click “PART 890 - Physical Medical Devices”. Click “890.3150 - Crutch”. We see that the Crutch is 510(k) Exempt and GMP Exempt and the description directs the reader to the Device Registration and Listing Website.

   NOTE: This is the same information found if the innovator had searched the CDRH Database and clicked on a similar device

3. Once a similar device is found and classification is known follow the Regulatory Pathway Flowchart to verify the Regulatory Pathway.
4. If the device is 510(k) Exempt the establishments or facilities associated with the production and distribution of the

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device (i.e. the company and manufacturer) must register with the FDA ***annually*** for the fiscal year which includes paying an annual fee. The establishments must also list all the devices that are made there.

NOTE: More information can be found on the FDA site 'Who Must Register List and Pay the Fee?'

5. If the device is not GMP exempt, the manufacturer will need to follow the Current Good Manufacturing Practices for Medical Devices, more information found here.

CLASS II DEVICE:

1. Once a suitable device(s) is found, if Class II, use the unique Product Codes to search the 510(k) Database. The predicate's 510(k) submission will provide insight into necessary steps toward submission such as special controls, manufacturers, clinical trials and testing.

   NOTE: If there are Special Controls Guidance Documents they will be listed by the device classification name, the Guidance Document is necessary to follow prior to submission.

   NOTE: If the device is Class II 510(k) Exempt, 510(k) Database won't help. Use guidance documents and industry standards to guide development. Still need to follow design controls.

2. As a step towards understanding the regulations on the device, record the Regulation Number for device and use this to search the Electronic Code of Federal Regulation (e-CFR) to find the most up to date regulations for the technology.

   NOTE: These regulations dictate the minimum quality standards that must be followed.

   Alternatively, searching the FDA Code of Federal Regulation (CFR) Title 21 Database for regulatory information is an option.

   NOTE: This will also provide a link to the ECFR website.

3. Once a predicate device(s) is found and classification is known follow the Regulatory Pathway Flowchart to verify the Regulatory Pathway

4. If there are multiple predicate devices, refer to the Predicate Device Decision Matrix Worksheet in order to help choose the most viable predicate

   NOTE: The FDA does not encourage the use of "split predicates", making it important to choose one. Instead, it is best to choose the best available predicate device and have other "reference devices" more information in the Regulatory Strategy Supplemental Reading.

CLASS III DEVICE:

1. Once a similar device(s) is found, if Class III, the device will not be able to act as a predicate device. The innovator will need to determine if the claims (IFU) or technical characteristics can be adapted to fit an approved Class II device and follow the 510(k) pathway or if a De Novo or Premarket Approval (PMA) will need to be pursued.

2. Once a similar device(s) is found and classification is known follow the Regulatory Pathway Flowchart to verify the Regulatory Pathway

3. A PMA is the most rigorous FDA application and requires large investments of time and money from the innovator, if the device can be reclassified to Class II and go through a De Novo application the investment can be reduced. To mitigate risk, can approach FDA with Q-submission/Pre-Submission to receive feedback.

   NOTE: More information can be found in the Regulatory Strategy Supplemental Reading

REGULATORY PLAN

Follow and Complete Regulatory Plan Worksheet and return to TREAT for discussion.

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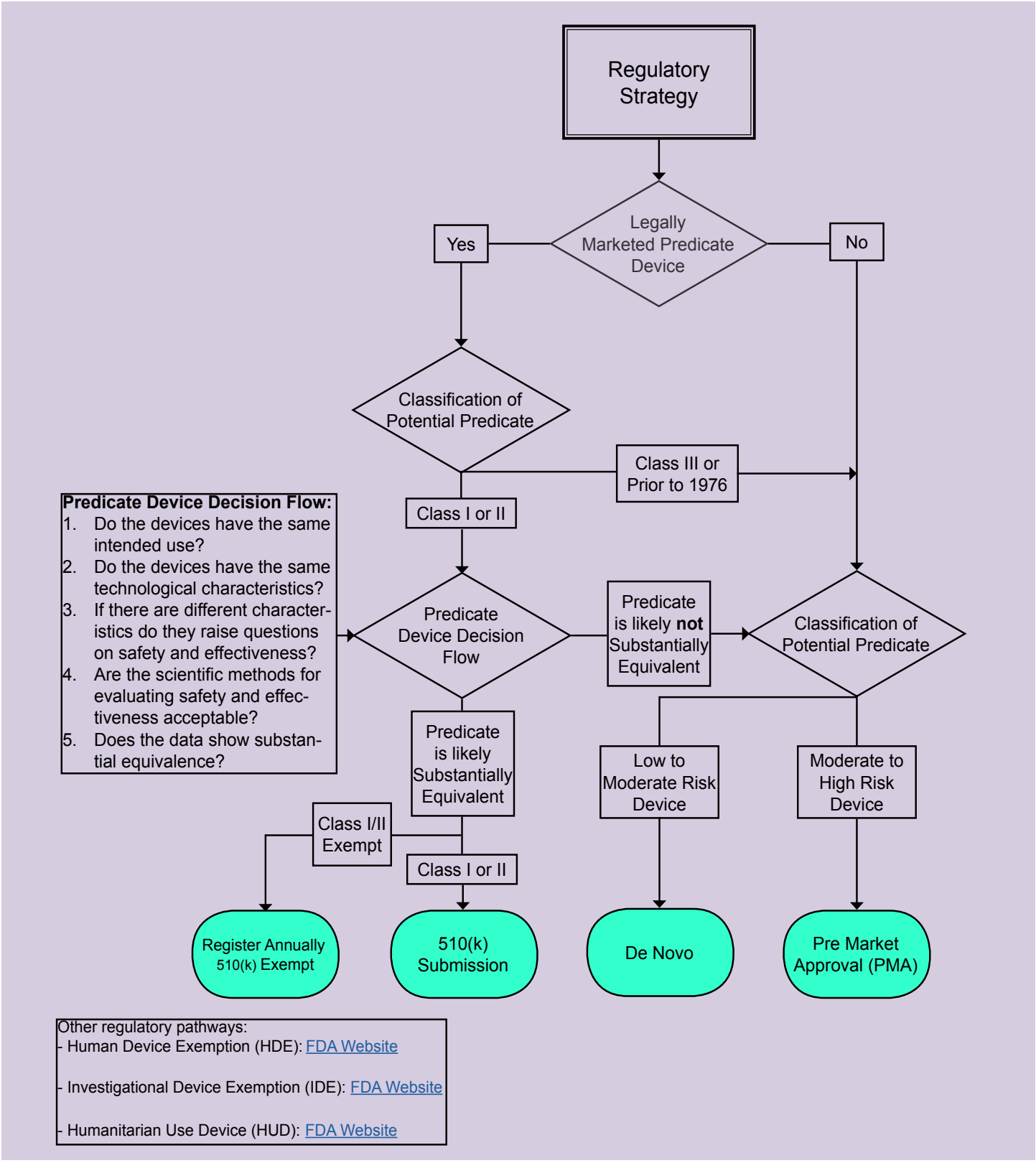
Regulatory Strategy

Regulatory Flow Chart



Predicate Device Decision Flow:

1. Do the devices have the same intended use?
2. Do the devices have the same technological characteristics?
3. If there are different characteristics do they raise questions on safety and effectiveness?
4. Are the scientific methods for evaluating safety and effectiveness acceptable?
5. Does the data show substantial equivalence?

Other regulatory pathways:

- Human Device Exemption (HDE): FDA Website
- Investigational Device Exemption (IDE): FDA Website
- Humanitarian Use Device (HUD): FDA Website

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