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Georgetown-Howard Universities
Center for Clinical and Translational Science

Investigational Drug, Device and Biologic Development

Mary Anne Hinkson
Vice President, Research Operations
MedStar Health Research Institute

DRUG DEVELOPMENT

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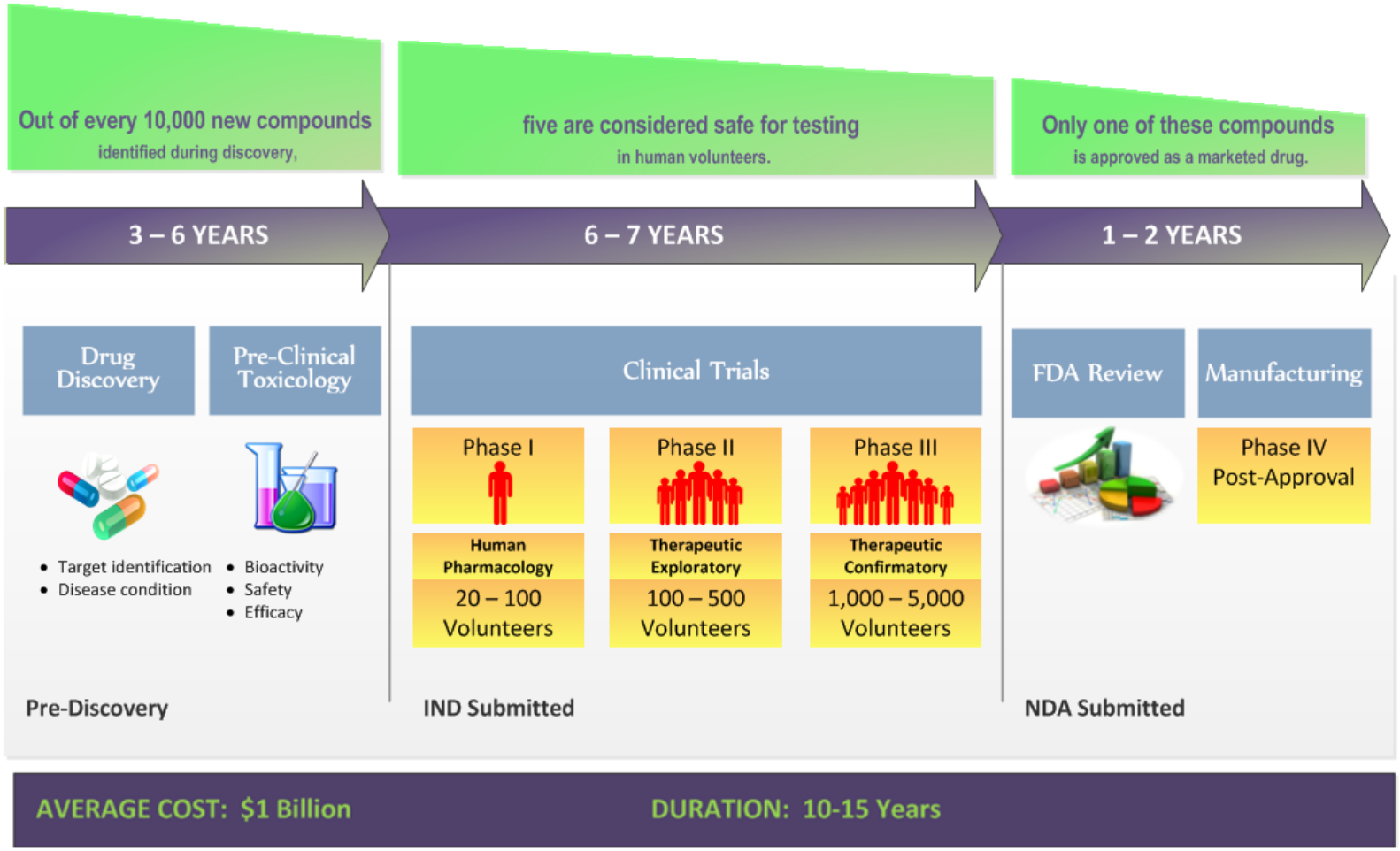
Drug Development Overview



BIOLOGIC DEVELOPMENT

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Biologic Development

- What is a biologic product?
  - Biological products, like drugs, are used for treatment, prevention or cure of disease in humans
  - Virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product applicable to the prevention, treatment or cure of a disease or condition of human beings
- Are biologic development requirements different than the requirements for a new drug product?
  - Biological products are a subset of drugs
  - Following initial laboratory and animal testing that show investigational use in humans is reasonably safe, biological product (like drugs) can be studies in humans under an investigational new drug application (IND)

Biologic Development

- What center has the regulatory responsibility for therapeutic biological products?
  - Both FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER)
  - FDA approval to market a biologic is granted by issuance of a biologics license

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DEVICE DEVELOPMENT

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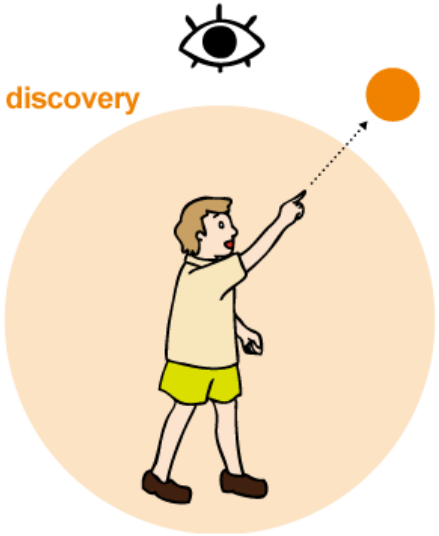
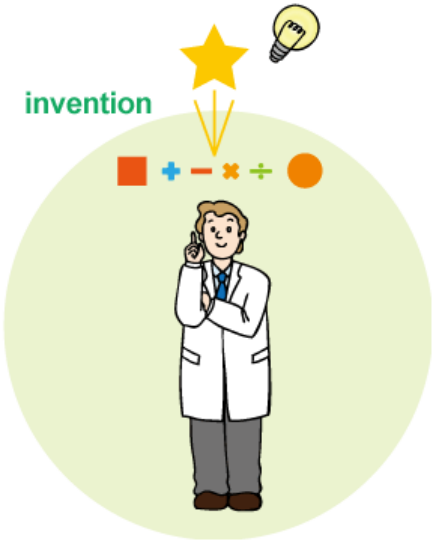
Device Development

Drugs are Discovered



Discovery is recognizing something that already exists for the first time, that nobody has found before

Devices are Invented



Invention is creating something totally new with one's own ideas and development

Medical Device technology is constantly evolving

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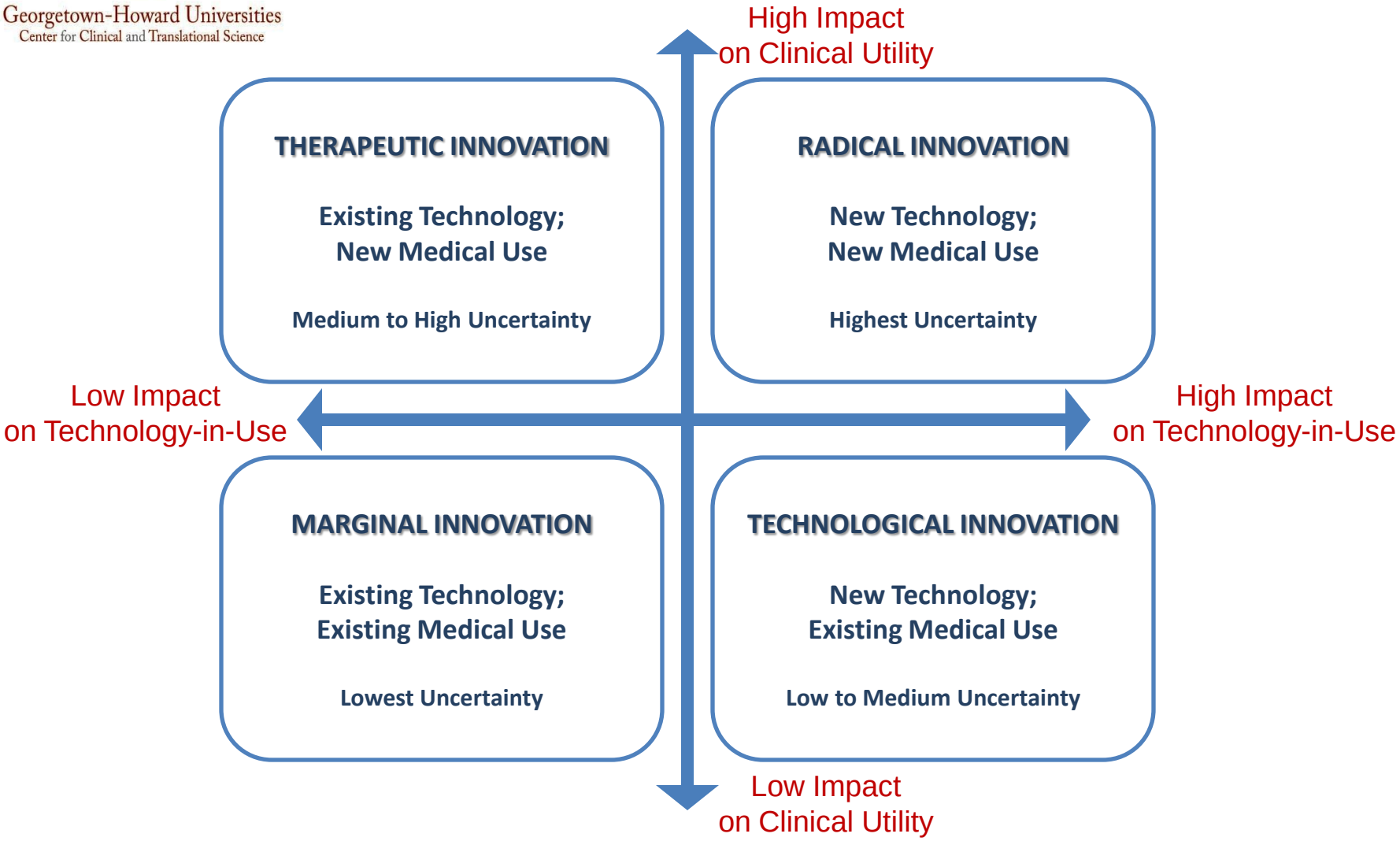
PRODUCT INNOVATION

Medical Device



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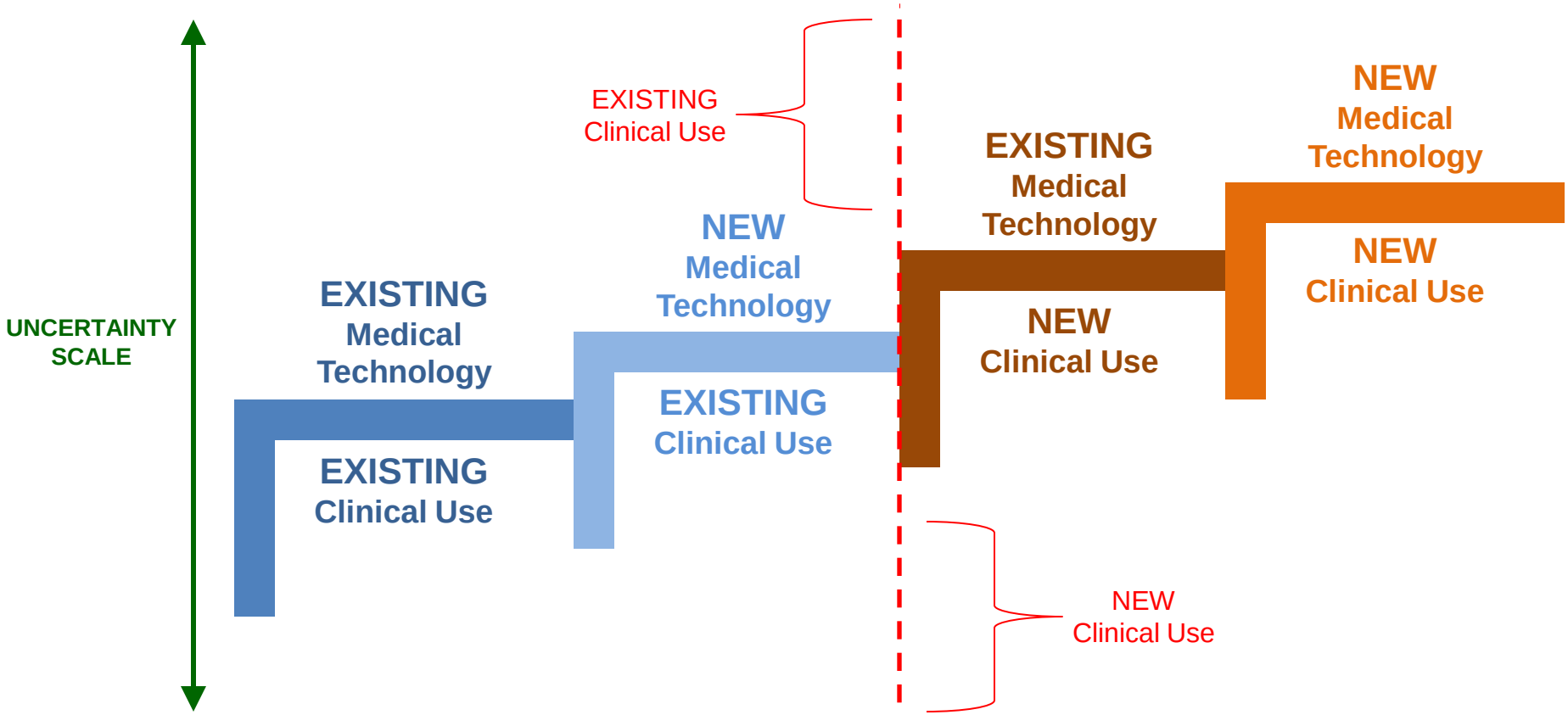
DEVELOPMENT RISK

Medical Device



Medical Device

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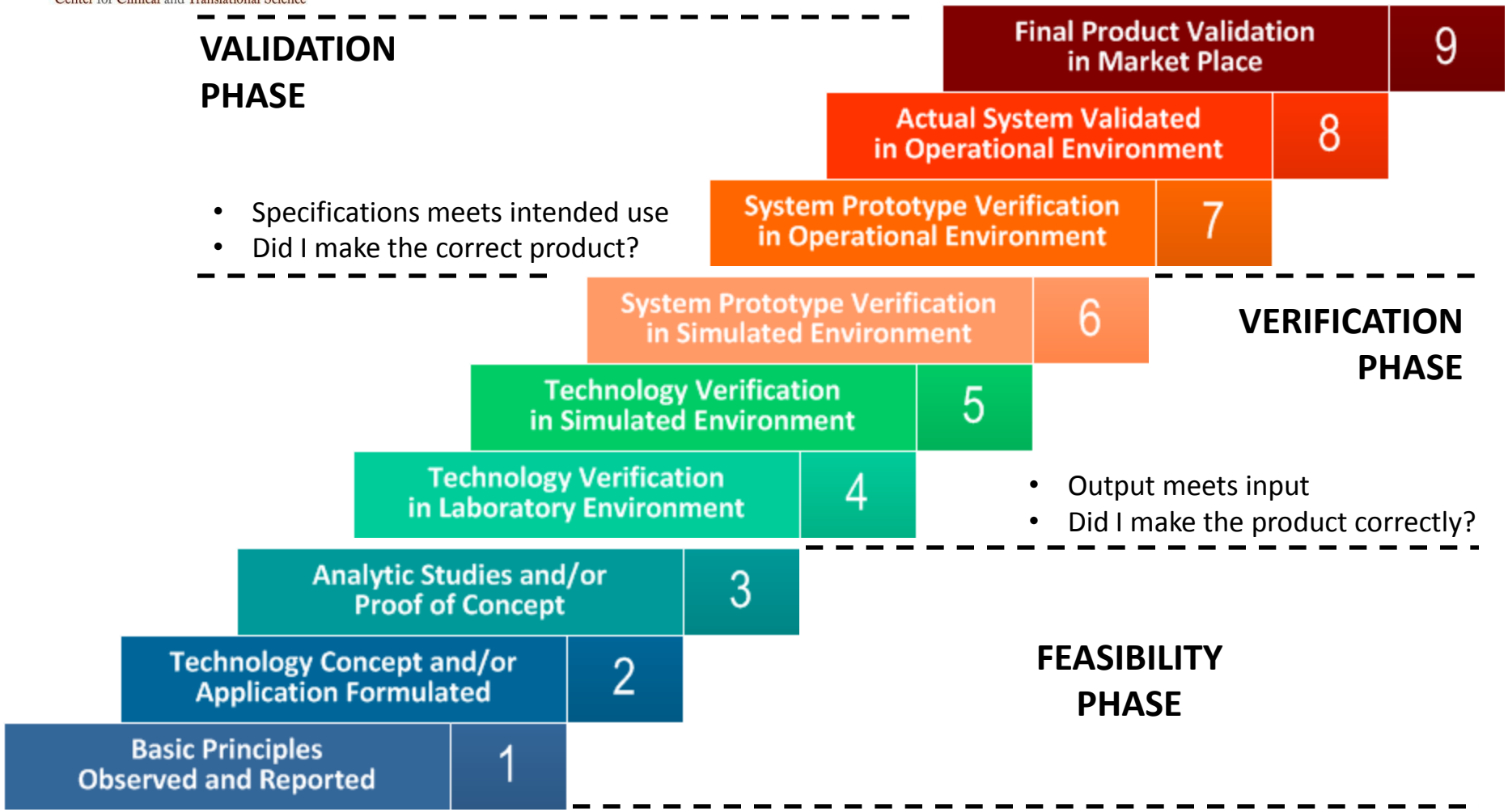

Medical Device Overview

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Class I	Class II	Class III
• Low Risk	• Medium Risk	• High Risk
• ~ 55% of Devices	• ~ 40% of Devices	• ~ 5% of Devices

REGISTRATION	CLEARANCE TO MARKET DEVICE	APPROVAL TO MARKET DEVICE

Medical Device Overview

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Class I

- Low Risk
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Class II

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Class I
Class II

510(k) (section of act)

Substantially Equivalent to Predicate Device

Class III

- High Risk
- ~ 5% of Devices

Class II
Class III

Pre-Market Approval (PMA)

Reasonable Assurance of Safety and Efficacy

REGISTRATION | **CLEARANCE TO MARKET DEVICE** | **APPROVAL TO MARKET DEVICE**

Medical Device Overview

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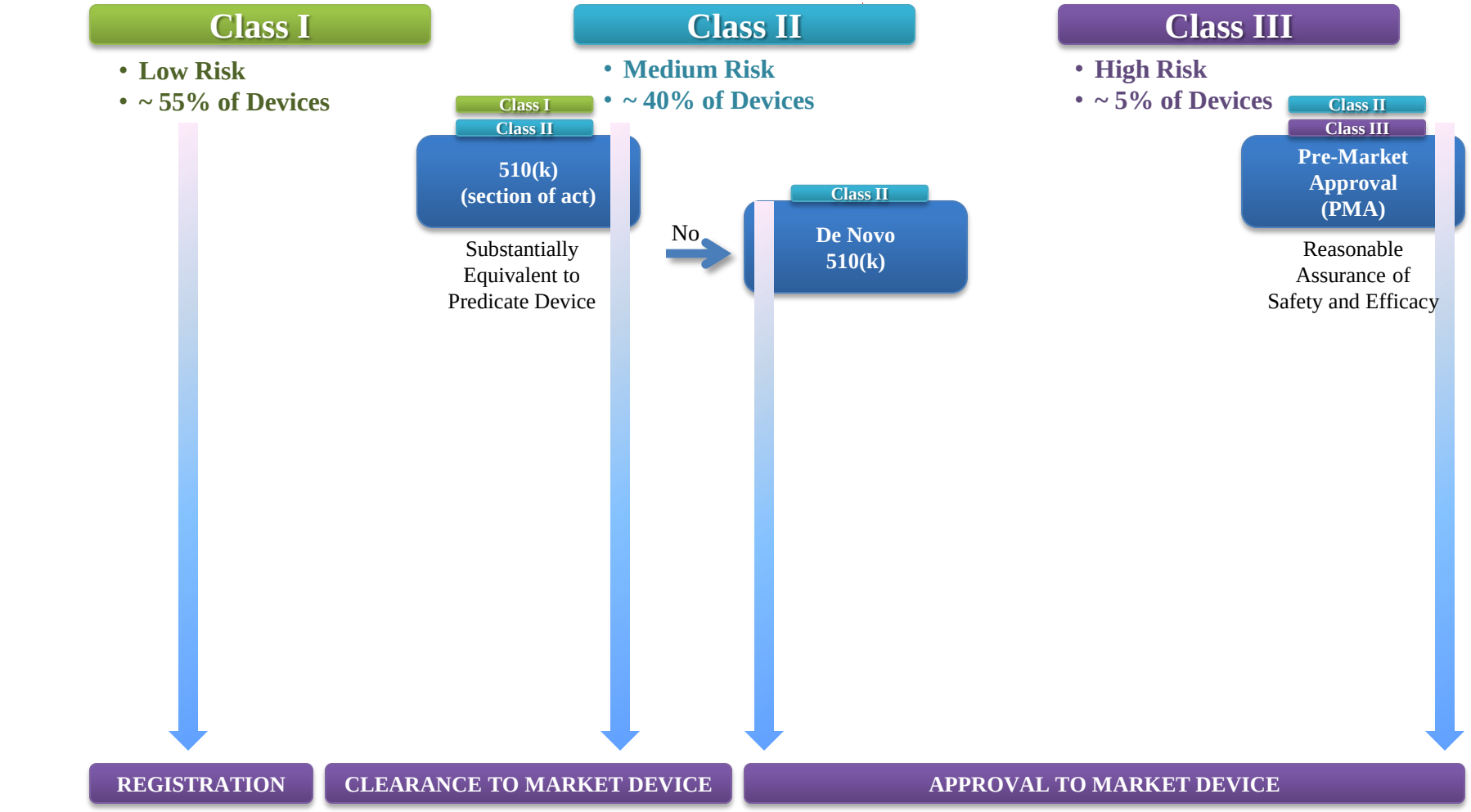

Medical Device Overview

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Class I

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- ~ 55% of Devices

Class II

- Medium Risk
- ~ 40% of Devices

Class I
Class II
510(k) (section of act)

Substantially Equivalent to Predicate Device

No

Class II
De Novo 510(k)

Class III

- High Risk
- ~ 5% of Devices

Class II
Class III
Humanitarian Device Exemption (HDE)

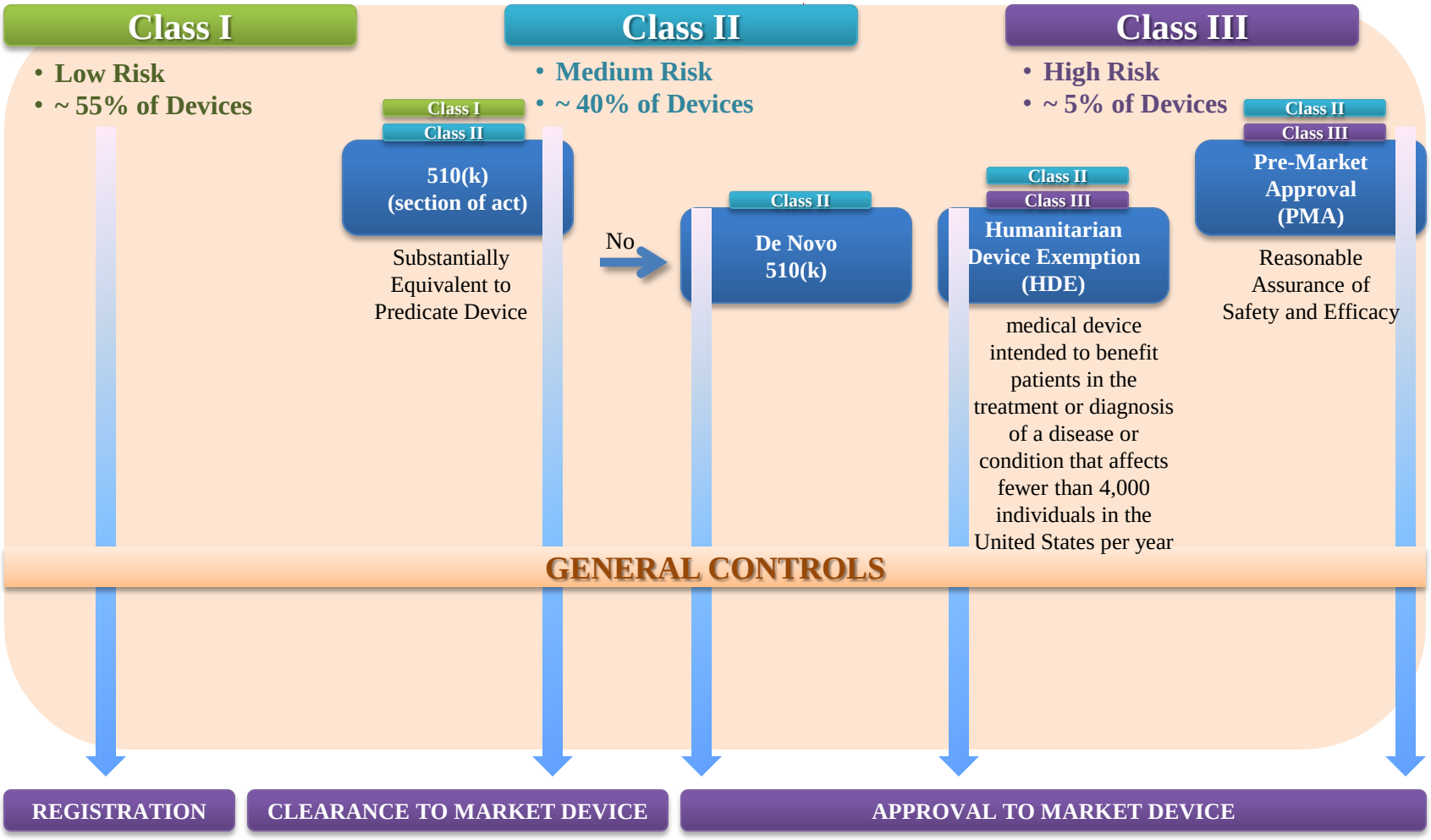
medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year

Class II
Class III
Pre-Market Approval (PMA)

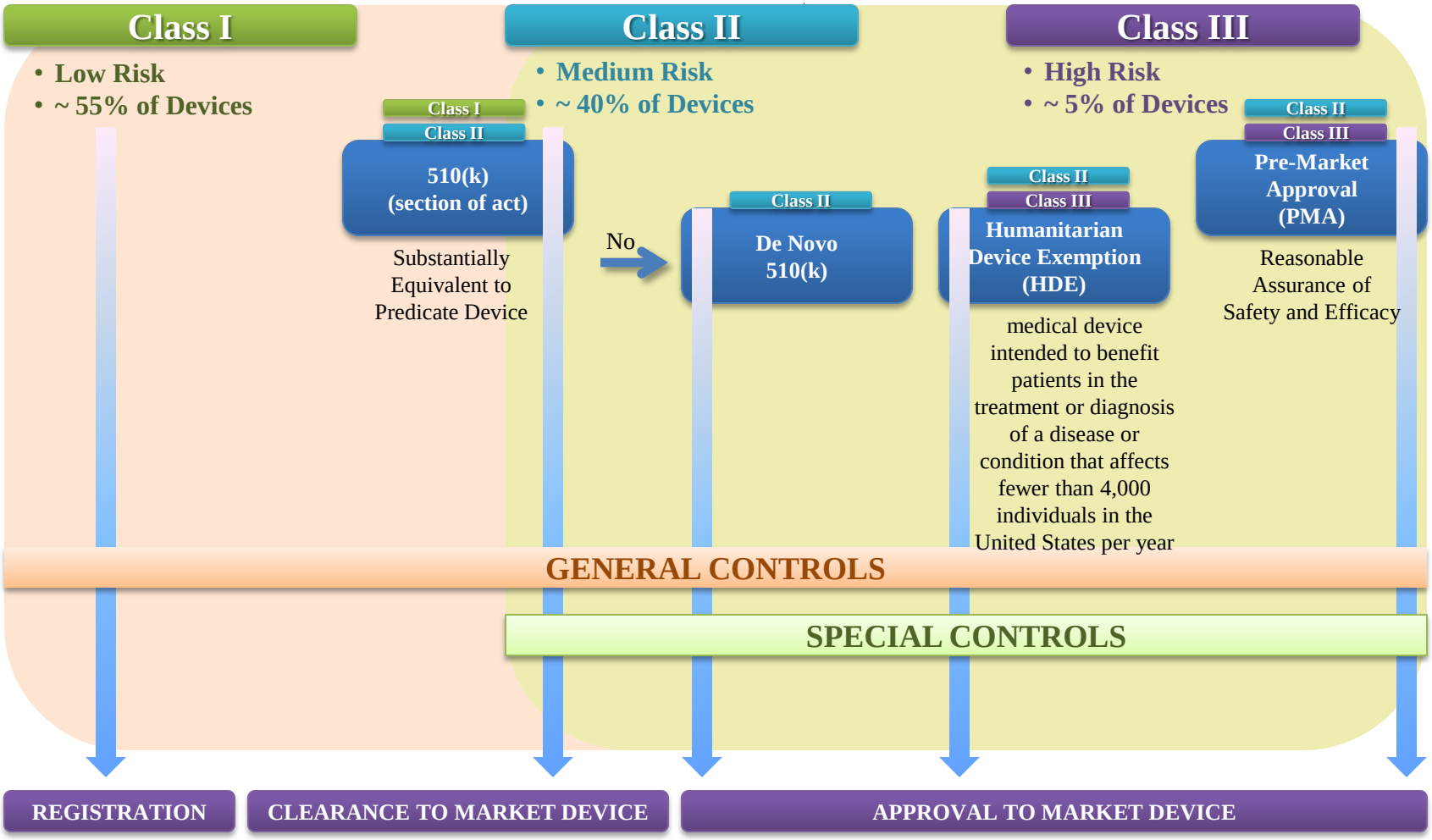
Reasonable Assurance of Safety and Efficacy

REGISTRATION | **CLEARANCE TO MARKET DEVICE** | **APPROVAL TO MARKET DEVICE**

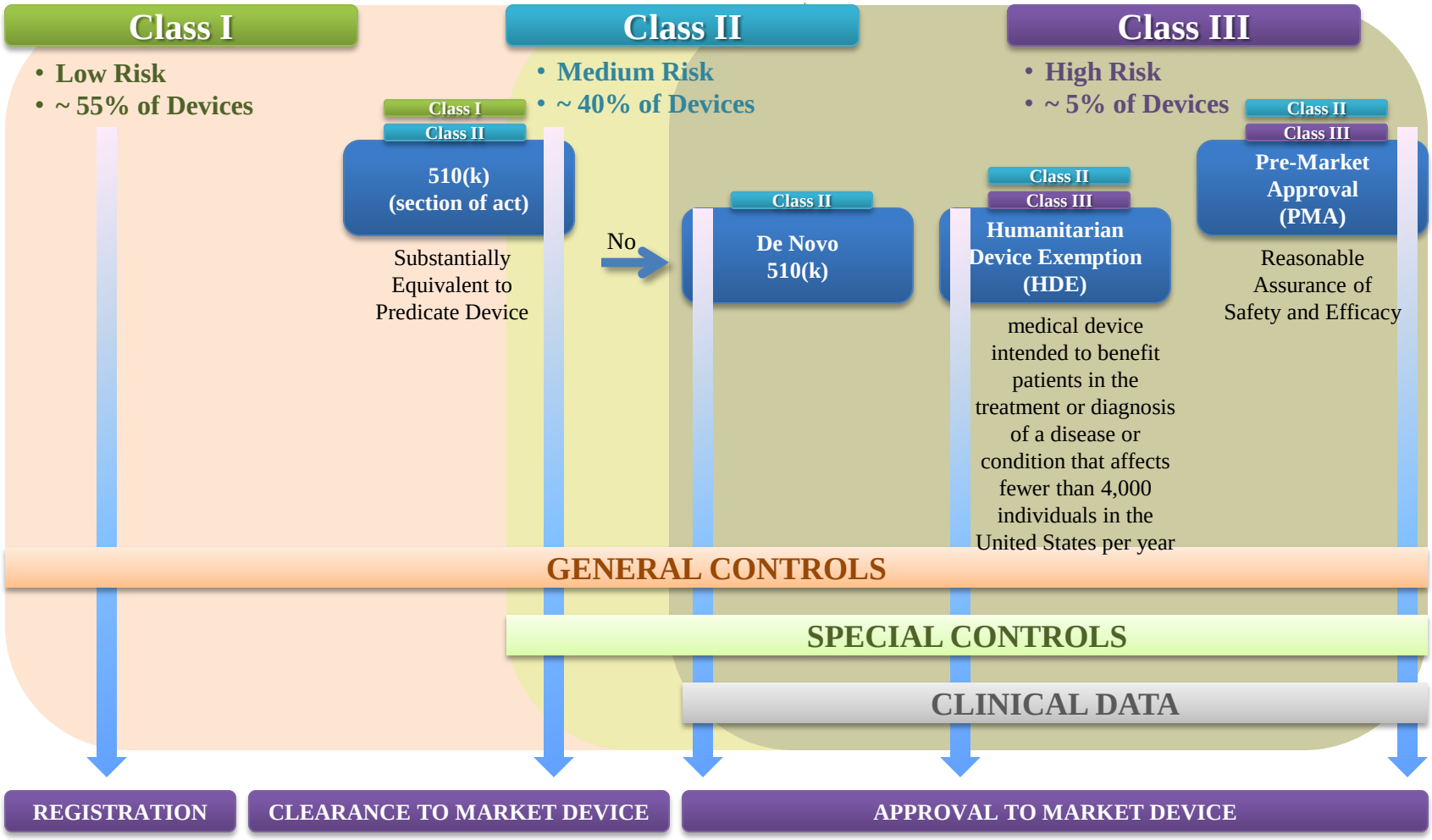
Medical Device Overview



Medical Device Overview



Medical Device Overview



Medical Device Overview

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GENERAL CONTROLS

- 501: Adulterated Devices
- 502: Misbranded Devices
- 510: Registration
  - Establishment Registration and Device Listing
  - Pre-Market Notification; 510(k)
- 519: Records and Reports
  - Adverse Event Report
  - Device Tracking
  - Unique Device Identification System
  - Reports of Removal and Corrections

Medical Device Overview

Class I

- **Low Risk**
- **~ 55% of Devices**

Class II

- **Medium Risk**
- **~ 40% of Devices**

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- **High Risk**
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SPECIAL CONTROLS

- Performance standards
- Post-market surveillance
- Patient registries
- Special labeling requirements
- Premarket data requirements
- Guidelines

Medical Device Overview

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CLINICAL DATA

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Types of Medical Devices

Types of Medical Devices

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See Related Information

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2017]
[CITE: 21CFR872.6855]

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

PART 872 -- DENTAL DEVICES

Subpart G--Miscellaneous Devices

Sec. 872.6855 Manual toothbrush.

(a) *Identification.* A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

Types of Medical Devices

Types of Medical Devices

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2017]
[CITE: 21CFR892.1710]

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 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1710 Mammographic x-ray system.

(a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

ical Devices

Guidance for Industry

Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters

Document issued on: November 30, 1998

If the sponsor is requesting the addition of device-specific claims regarding the clinical performance of the device, clinical data sufficient to statistically support such claims should be submitted. Consult the Urology and Lithotripsy Devices Branch for guidance on the appropriate study design to address the particular clinical performance claims proposed for the device.

Center for Devices and Radiological Health
CDRH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

Risk of Device Studies

- We determined the risk of the medical device
- What is the risk of the medical device study (protocol)?
  - Significant Risk (SR) Study
  - Non-significant Risk (NSR) Study
- What is a Significant Risk Study?
  - Intended as an implant
  - Supporting or sustaining human life
  - Substantial importance in diagnosing, curing, mitigating or treating disease
  - Presents a potential for serious risk to the health, safety or welfare of subject
- What is a Non-Significant Risk Study?
  - Does not meet the definition of a significant risk device study

Risk of Device Studies

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☐ Significant Risk Study
☑ Non-Significant Risk Study

Device

- Change in “image processing” (to mean algorithms); Class II device

Study Design

- Imaging in OR during brain surgery
- Perform brain imaging with 510(k) cleared algorithms and determine diagnosis and surgery (primary diagnosis)
- Perform brain imaging with investigational algorithms; compare to 510(k) cleared algorithms

☑ Significant Risk Study
☐ Non-Significant Risk Study

Device

- Change in “image processing” (to mean algorithms); Class II device

Study Design

- Routine mammography study
- Perform routine mammography with 510(k) cleared algorithms and determine diagnosis (primary diagnosis)
- Perform routine mammography with investigational algorithms; compare to 510(k) cleared algorithms

Insurance Reimbursement

Medical Safety	Clinical Efficacy
• FDA validates safety and efficacy of new device	

Medical Safety	Clinical Outcome	Economic Outcome
• CMS considers patient need and medical necessity		
• CMS will not approve new costly procedure or device if current treatment gives similar outcome		
• CMS will approve new device that demonstrates superior results		
• CMS will approve new procedure if greatly needed and no current alternatives		
• Health economics must justify more costly device with better patient outcome		

Insurance Reimbursement

- Device receiving 510(k) Clearance is substantially equivalent to currently marketed product, so
  - Device would fall under current reimbursement coverage, code and payment
  - Argument for higher payment for device is illogical

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Let's Take a LOOK at some

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