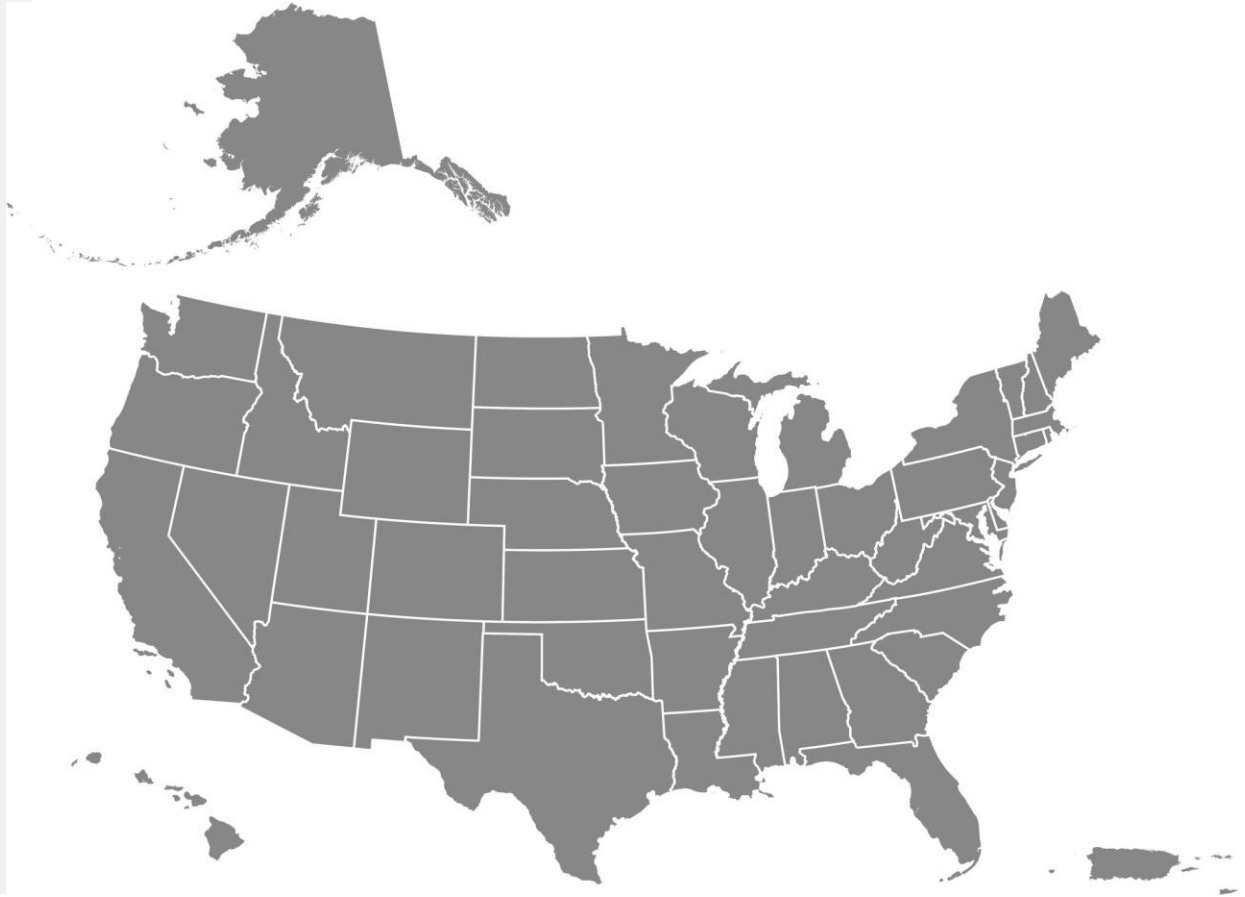
Medical Devices

US FDA

History & Device Classes



Current as of: 032023

Medical Device Definition

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:

- 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."

Medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits.

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Medical Device History and Framework

- FDA History
  - Medical Device and Radiological Health Regulations Come of Age

- Device Laws & Regulations
  Code of Federal Regulations (eCFR, Title 21 FDA, Section 800s)

- Device Guidance
  Guidance Doc database

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FDA Medical Device Classes

Medical Devices Classification

Class	Risk	Examples	Safety / Effectiveness Controls	Regulatory Pathway
I	Low	Tongue depressor, hospital beds	**General Controls** - With Exemption - Without Exemption	**Self Registration** Or **510(k)**
II	Medium	Absorbable suture, blood pressure cuffs	**General controls** - With Exemption - Without Exemption **Special controls** - With Exemption - Without Exemption	• Most class II devices are approved under a **510(k)** pre-market notification submission. • Few devices of class II are approve under **PMA** • 10-15% devices require **clinical trial**
III	Highest	Implantable pacemaker, coronary stent	**General controls** **Special controls** **Pre-market authorization**	**Pre-market approval (PMA)** Almost all require clinical Data

FOCUS **Product Classification Database** - Link

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FDA Device Applications

- Applications Types
  - **IDE** – Investigational Device Exemption
  - **PMA** – Premarket Approval
  - **510(k)**
  - **510(k) Exempt**
  - **De Novo** - A new medical device with no predicate device is by default classified as Class III and requires a PMA. A De Novo premarket submission is a manufacturer's request for the FDA to reclassify such as device into a lower risk Class II or Class I category. It avoids a PMA and may possibly also avoid a 510(k) submission.
  - **HDE** – Humanitarian Device Exemption
  - **CDE** – Custom Device Exemption
- Submission Formats: PDF

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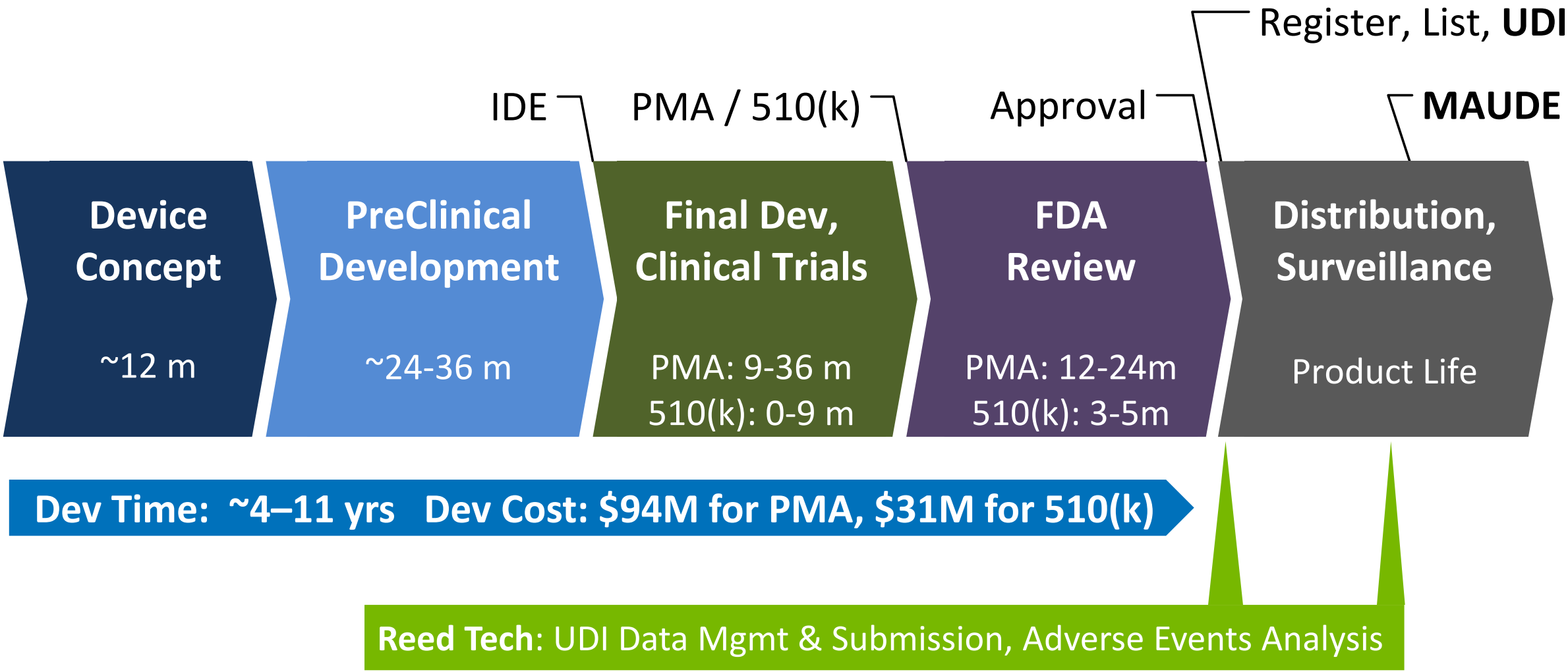
Medical Device Development Process



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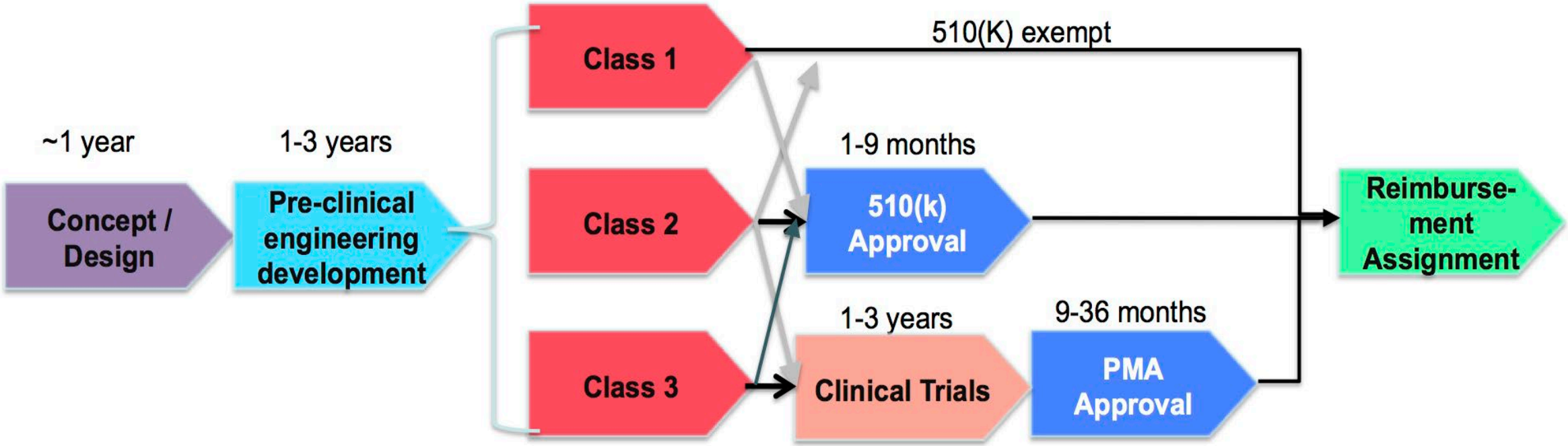
Medical Device Development Process



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Device ID - Unique Device Identification (UDI)

A UDI is a globally unique numeric or alphanumeric code that consists of two parts:

- **Device Identifier (DI)**, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- **Production Identifier (PI)**, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - ***manufactured date***
  - ***expiration date***
  - ***lot or batch number***
  - ***serial number***
  - **distinct identification code** (DIN) required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

UDI = DI + PI

(01)00855361005016(11)140924(17)180924(10)B35(21)S123

Source: FDA; GS1 UDI example

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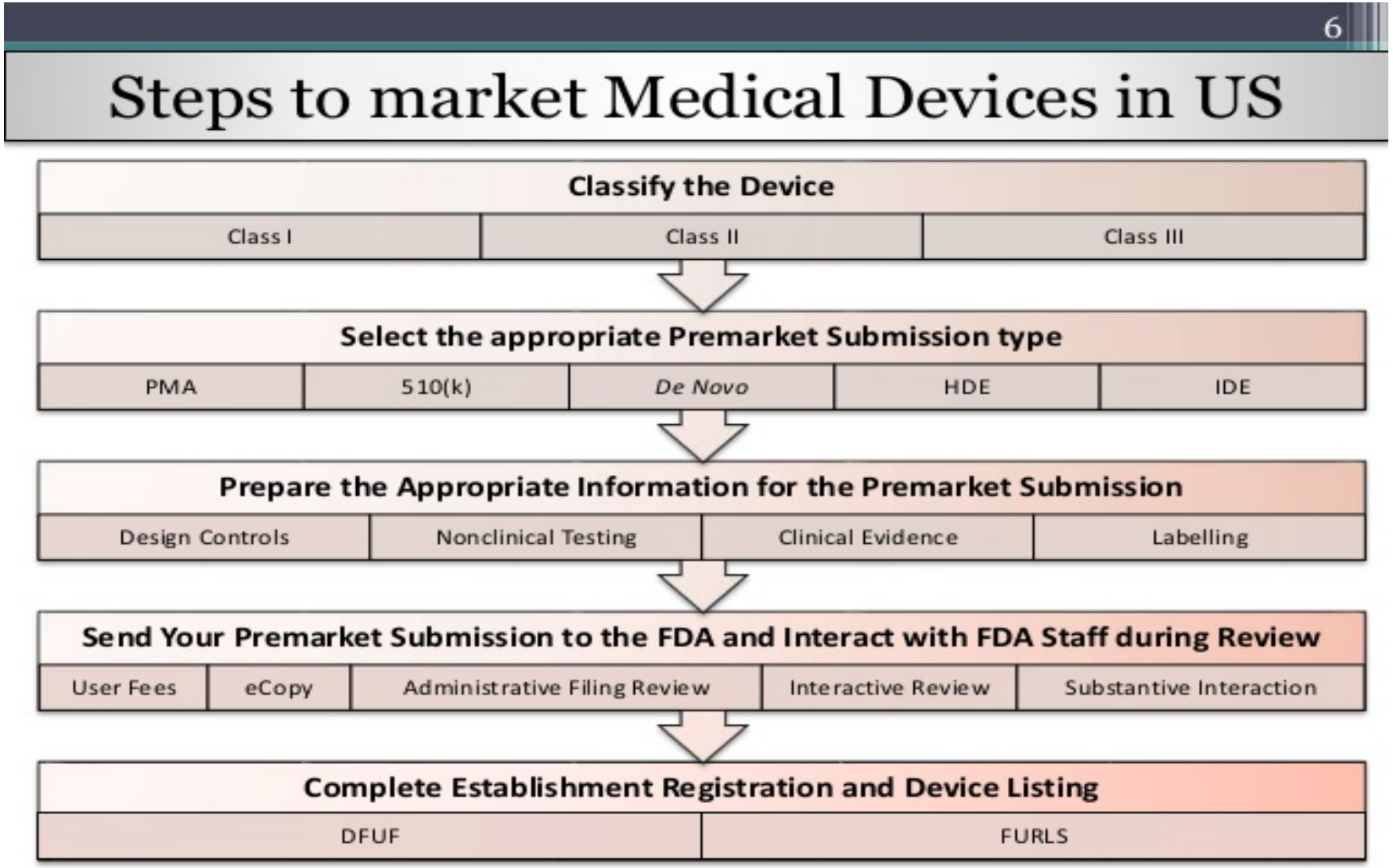
FDA Authorization Steps



UDI

- Submit to GUDID
- Place On Label

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Authorization Process Summary

A Medical Device Manufacturer must:

1. Determine FDA product Class and follow corresponding pathway for FDA marketing approval to commercially distribute a product:
   - Class III - Premarket Application (PMA) approval; typically need clinical trials
   - Class II - Premarket Notification 510(k) clearance: need a predicate device
   - Class I - 510(k) Exemption
2. Pay User Fees for PMA and 510(k) (per submission)
3. Pay Establishment Fees (annually)
4. Register Establishment(s) (annually)
5. List Products for each Establishment (annually)

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Authorization Process Summary Cont'd

6. Report products to the FDA GUDID before commercial distribution per the FDA UDI Compliance Date phased implementation
   - If necessary, create a Dun & Bradstreet DUNS number for their company
   - Subscribe to an FDA-approved Issuing Agency (GS1, HIBCC, ICCBBA) and receive a Company identifier
   - Assign a Device Identifier to the product
   - Create a FDA GUDID account & Submit device records consisting of 57 attributes each
7. Label a Product (include the UDI)
   - Apply the full product UDI (Device Identifier and any Production Identifiers) in Human-readable and AIDC (e.g., barcode) format to the product and packaging labels
   - If the product is used on multiple patients and reprocessed between patients, then permanently apply the UDI in either or both Human-readable and AIDC format to the product
8. Include UDI in various FDA reports, as applicable, e.g., Annual Reports, DHR, Complaints, MDR, Recalls, Service, Tracking, Post Marketing Surveillance

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