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## 05 February 2015 – part 8

**PMA, 510k, IDE**

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# USA/FDA Pre Market Approval System - PMA, Pre Market Notifcation - 510k, Investigational Device Exemption - IDE

- Regulation Overview
  Device Classification
- 510k
- PMA
- IDE / HDE

# CDRH - Center for Devices and Radiological Health

Responsible for regulating firms who:

- manufacture,
- repackage,
- relabel,
- and/or import

medical devices sold in the United States

# Basic regulatory requirements

- ✓ Establishment Registration
- ✓ Medical Device Listing
- ✓ Premarket Notification 510(k)
- ✓ Premarket Approval (PMA)
- ✓ Investigational Device Exemption (IDE)
- ✓ Labeling
- ✓ Medical Device Reporting

# The FDA has established classifications

- ✓ classifications for ~ 1'700 different types of devices
- ✓ grouped into 16 medical specialties > panels
- ✓ devices assigned to one of three regulatory classes
- ✓ classes based on level of control to assure safety and effectiveness
- ✓ classification depends on the intended use of the device and also upon indications for use

# The indications for use is a subset of the intended use

intended use
of a scalpel is to cut tissue

indications for use, in the device's labelling
could be « for making incisions in the cornea »

A discussion of the meaning of intended use is contained in
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)].

# Device classification is risk based

- ✓ risk posed to the patient
- ✓ risk posed to the user

# Risk based & classification

- ✓ The class to which the device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market

# Risk based & classification

| | | |
|---|---|---|
| Class I | lowest risk | ~ 30% |
| Class II | risk moderate | ~ 60% |
| Class III | greatest risk | ~ 10% |

# Examples

| | |
|---|---|
| Class I | elastic bandages<br>examination gloves<br>hand-held surgical instruments<br>mechanical wheelchairs |
| Class II | powered wheelchairs<br>infusion pumps<br>surgical drapes<br>bone screw |
| Class III | heart valves<br>silicone gel-filled breast implants<br>implanted cerebella stimulators<br>osseous implants<br>peacemakers<br>dental laser |

# Classification & registration

| | | | |
|---|---|---|---|
| Class I | No need for FDA clearance | Registered device and company | Self-register fees |
| Class II | FDA clearance required | 510k | Pre-market notification |
| Class III | FDA approval required | PMA | Pre-market approval process |

# Classification & level of regulatory controls

| | | |
|---|---|---|
| Class I | General Controls | least regulatory control |
| Class II | General Controls and Special Controls | |
| Class III | General Controls and Premarket Approval | most stringent regulatory control |

# General controls - sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug and Cosmetic Act

- Basic provisions and authorities
- Providing the FDA with the means of regulating devices
- To ensure their safety and effectiveness
- Applying to all medical devices
- And including provisions that relate to, for instance described in the :
  - ✓ misbranding
  - ✓ device registration and listing
  - ✓ premarket notification
  - ✓ banned, restricted devices
  - ✓ notification, including repair, replacement, or refund
  - ✓ records and reports
  - ✓ good manufacturing practices

# Special controls

- General controls alone are insufficient
- Not providing reasonable assurance of safety and effectiveness
- Devices for which there is sufficient information to establish special controls
- Special controls are usually device-specific and include:

  - ✓ Performance standards
  - ✓ Postmarket surveillance
  - ✓ Patient registries
  - ✓ Special labeling requirements
  - ✓ Premarket data requirements
  - ✓ Guidelines

# How device classification is determined?

Two ways to find the regulation number:

1° classification database
2° device panel

# Classification panels & regulations

| | |
|---|---|
| 864 | Hematology and Pathology |
| 866 | Immunology and Microbiology |
| 882 | Neurology |
| 884 | Obstetrical and Gynecological |
| 886 | Ophthalmic |
| 888 | Orthopedic |
| 890 | Physical Medicine |
| 892 | Radiology |

# Classification panels & regulations

| | |
|---|---|
| 868 | Anesthesiology |
| 870 | Cardiovascular |
| 862 | Clinical Chemistry and Clinical Toxicology |
| 872 | Dental |
| 874 | Ear, Nose, and Throat |
| 876 | Gastroenterology and Urology |
| 878 | General and Plastic Surgery |
| 880 | General Hospital and Personal Use |

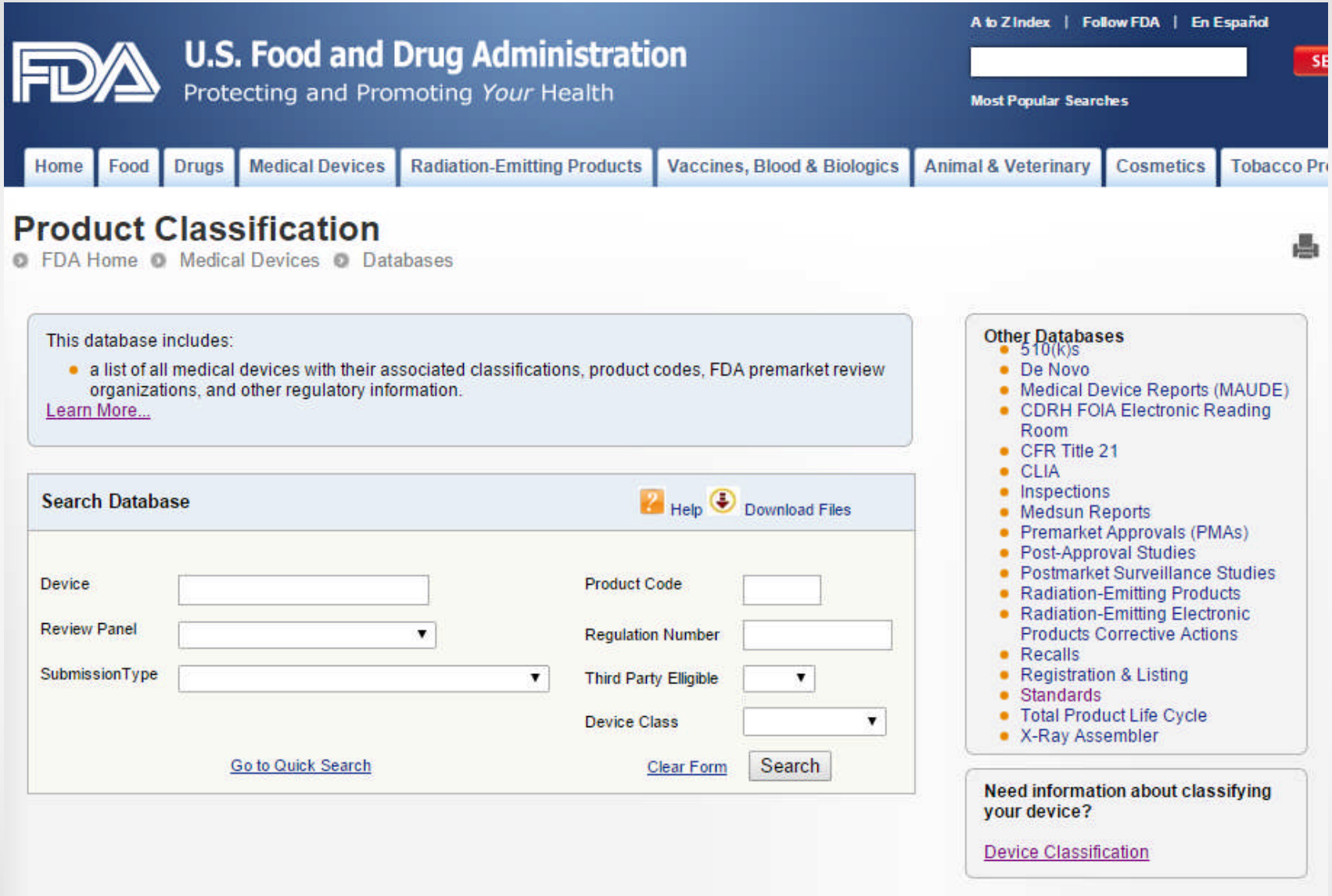
# Product Code Classification Database

Contains:

- ✓ medical device names
- ✓ associated product codes
- ✓ information developed by CDRH

Then, name and product code identifies the generic category of a device for FDA.

Based upon the medical device product classification designated under 21 CFR Parts 862-892.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Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Product Classification
FDA Home
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Databases
This database includes:
a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.
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De Novo
Medical Device Reports (MAUDE)
CDRH FOIA Electronic Reading Room
CFR Title 21
CLIA
Inspections
Medsun Reports
Premarket Approvals (PMAs)
Post-Approval Studies
Postmarket Surveillance Studies
Radiation-Emitting Products
Radiation-Emitting Electronic Products Corrective Actions
Recalls
Registration & Listing
Standards
Total Product Life Cycle
X-Ray Assembler
Need information about classifying your device?
Device Classification

# Product Classification

FDA Home ▸ Medical Devices ▸ Databases

1 to 5 of 5 Results

*lithotriptor*

Results per Page 5

New Search | Export to Excel | Download Files | More About Product Classification

| Product Code | Device | | Regulation Number | Device Class |
|---|---|---|---|---|
| LQC | Lithotriptor, Biliary Mechanical | Mechanical Lithotriptor | 876.4500 | 2 |
| FFK | Lithotriptor, Electro-Hydraulic | Electrohydraulic Lithotriptor | 876.4480 | 2 |
| LNS | Lithotriptor, Extracorporeal Shock-Wave,Urological | Extracorporeal Shock Wave Lithotripter | 876.5990 | 2 |
| FEO | Lithotriptor, Ultrasonic | Electrohydraulic Lithotriptor | 876.4480 | 2 |
| FGK | Tripsor, Stone, Bladder | Mechanical Lithotriptor | 876.4500 | 2 |

New Search | Back To Search Results

| | |
|---|---|
| **Device** | Lithotriptor, Extracorporeal Shock-Wave,Urological |
| **Regulation Description** | Extracorporeal shock wave lithotripter. |
| **Regulation Medical Specialty** | Gastroenterology/Urology |
| **Review Panel** | Gastroenterology/Urology |
| **Product Code** | LNS |
| **Premarket Review** | Office of Device Evaluation (ODE)<br>Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)<br>Urology and Lithotripsy Devices Branch (ULDB) |
| **Submission Type** | 510(k) |
| **Regulation Number** | 876.5990 |
| **Device Class** | 2 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | No |

**Recognized Consensus Standards**

- IEC 61846 First edition 1998-04 Ultrasonics - Pressure pulse lithotripters - Characteristics of fields
- IEC 60601-2-36 Edition 2.0 2014-04 Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy

**Guidance Document**

- Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi

| | |
|---|---|
| **Third Party Review** | Not Third Party Eligible |

New Search | Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2014]
[CITE: 21CFR872.4200]

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 872 -- DENTAL DEVICES

Subpart E--Surgical Devices

Sec. 872.4200 Dental handpiece and accessories.

(a) *Identification.* A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) *Classification.* Class I.

[55 FR 48439, Nov. 20, 1990]

New Search | Help | More About 21CFR

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 A--General Provisions**

§ 872.1 - Scope.
§ 872.3 - Effective dates of requirement for premarket approval.
§ 872.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

**Subpart B--Diagnostic Devices**

§ 872.1500 - Gingival fluid measurer.
§ 872.1720 - Pulp tester.
§ 872.1730 - Electrode gel for pulp testers.
§ 872.1740 - Caries detection device.
§ 872.1745 - Laser fluorescence caries detection device.
§ 872.1800 - Extraoral source x-ray system.
§ 872.1810 - Intraoral source x-ray system.
§ 872.1820 - Dental x-ray exposure alignment device.
§ 872.1830 - Cephalometer.
§ 872.1840 - Dental x-ray position indicating device.
§ 872.1850 - Lead-lined position indicator.
§ 872.1870 - Sulfide detection device.
§ 872.1905 - Dental x-ray film holder.
§ 872.2050 - Dental sonography device.
§ 872.2060 - Jaw tracking device.

**Subpart C [Reserved]**

**Subpart D--Prosthetic Devices**

§ 872.3060 - Noble metal alloy.
§ 872.3070 - Dental amalgam, mercury, and amalgam alloy.
§ 872.3080 - Mercury and alloy dispenser.
§ 872.3100 - Dental amalgamator.
§ 872.3110 - Dental amalgam capsule.
§ 872.3130 - Preformed anchor.
§ 872.3140 - Resin applicator.
§ 872.3150 - Articulator.
§ 872.3165 - Precision attachment.
§ 872.3200 - Resin tooth bonding agent.
§ 872.3220 - Facebow.
§ 872.3240 - Dental bur.
§ 872.3250 - Calcium hydroxide cavity liner.

# Premarket Approval (PMA)

FDA Home ◉ Medical Devices ◉ Databases




New Search Back to Search Results

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

| | |
|---|---|
| **Trade Name** | EMS-SWISS DOLORCLAST |
| **Classification Name** | Generator, Shock-Wave, For Pain Relief |
| **Generic Name** | Orthopedic Lithotripter |
| **Applicant** | ELECTRO MEDICAL SYSTEMS (EMS SA) |
| **PMA Number** | P050004 |
| **Supplement Number** | S001 |
| **Date Received** | 03/18/2009 |
| **Decision Date** | 08/28/2009 |
| **Product Code** | NBN [ Registered Establishments With NBN ] |
| **Advisory Committee** | General & Plastic Surgery |
| **Supplement Type** | Normal 180 Day Track No User Fee |
| **Supplement Reason** | Process Change: Manufacturing |
| **Expedited Review Granted?** | No |
| **Combination Product** | No |

**Approval Order Statement**
Approval for a manufacturing site located at e. M. S. Electro medical systems, sa, nyon, switzerland.

# Checklist - product classification

- ✓ Device basic search term
- ✓ Device name
- ✓ Product code
- ✓ Regulation number

# USA/FDA Pre Market Approval System - PMA, Pre Market Notifcation - 510k, Investigational Device Exemption - IDE

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# Premarket notification – 510k

- ✓ Notification to the FDA
- ✓ Equivalence to predicate device / legally marketed device
- ✓ Traditional – special – abbreviated
- ✓ Concern class I, II and some III products

# Premarket notification - 510(k)

- ✓ Need of a consultant / expert
- ✓ Demonstrate « Substantial Equivalence »
- ✓ Establishment of a file
- ✓ Intended use
- ✓ Risk analysis
- ✓ Technical specifications
- ✓ Labeling, instructions for use
- ✓ Submission / third party review
- ✓ Approbation >> device clearance

# What is Substantial Equivalence?

- ✓ has the same intended use as the predicate; and
- ✓ has the same technological characteristics as the predicate; or
- ✓ has the same intended use as the predicate; and
- ✓ has different technological characteristics and the information submitted to FDA;
- ✓ does not raise new questions of safety and effectiveness; and
- ✓ demonstrates that the device is at least as safe and effective as the legally marketed device.

# 510(k) Decision Flowchart In the SE Guidance

1. Is the predicate device legally marketed?
2. Do the devices have the same intended use? Do the device have the same technological characteristics?
3. Do the different technological characteristics of the device raise different questions of safety and effectiveness?
4. Are the [scientific] methods acceptable?
5. Do the data demonstrate substantial equivalence?

# Substantial Equivalence Guidance

The term intended use means:

- ✓ the general purpose of the device or its function, and encompasses the indications for use

The term indications for use describes:

- ✓ the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended

21 CFR 814.20(b)(3)(i)

# The content of a 510(k) may include, but is not limited to:

- ✓ Statement of Intended Use for the device
- ✓ Description of how it operates
- ✓ Technical drawings, diagrams and pictures of the medical device
- ✓ Technical characteristics of the device compared to others already approved
- ✓ Proposed labelling, marketing materials and Instructions for Use
- ✓ Differences in the product compared to the "predicate" devices already approved by the FDA and how this may affect safety
- ✓ Testing data, including clinical data if applicable
- ✓ Maintenance and troubleshooting procedures, if applicable
- ✓ Compliance with any published Standards or Guidelines, if applicable

## 21 sections of a traditional 510(k) :

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description

## 21 sections of a traditional 510(k) :

12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other

# Alternate 510(k) Format – STED Pilot Program

- As an alternative, 510(k) may be submitted in the globally harmonized format described in the document:

  "Summary Technical Documentation for Demonstrating Conformity to Essential Principles of Safety and Performance of Medical Devices"

- Study Group 1 (SG1) of the Global Harmonization Task Force (GHTF)
- Comparison of the two format is recommended

# The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

## Guidance for Industry and Food and Drug Administration Staff

**Document issued on: July 28, 2014**

**The draft of this document issued on December 27, 2011.**

**This document supersedes FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.**

For questions for the Center for Devices and Radiological Health regarding this document, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

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

# USA/FDA Pre Market Approval System - PMA, Pre Market Notifcation - 510k, Investigational Device Exemption - IDE

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# PreMarket Approval – PMA

- ✓ Process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices
- ✓ Class III:
  - supports or sustains human life
  - potential unreasonable risk of illness or injury
- ✓ New devices with no equivalence #510K
- ✓ Some transitory class III devices

NB: 21 CFR Part 814, Premarket Approval

# PMA - Data Requirements

Technical Sections:

- ✓ The technical sections containing data and information should allow FDA to determine whether to approve or disapprove the application.
- ✓ These sections are usually divided into non-clinical laboratory studies and clinical investigations

# PMA - Data Requirements

Non-clinical Laboratory Studies' Section:

- ✓ Non-clinical laboratory studies' section includes information on:
  microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests

- ✓ Non-clinical studies for safety evaluation must be conducted in compliance with 21CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies)

# PMA - Data Requirements

## Clinical Investigations' Section:

- ✓ Clinical investigations' section includes:
  study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations
- ✓ Any investigation conducted under an Investigational Device Exemption (IDE) must be identified as such

NB: A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and cannot be marketed.

# Premarket Approval Application Content

I. General information
II. Table of content - to be updated with each submission in designated format
III. Summary of safety and effectiveness data
IV. Device description
V. Manufacturing information
VI. Certification of of conformance, reference to, and status of compliance with any performance standards
VII. Non-critical laboratory studies
VIII. Clinical studies
IX. Bibliography / references
X. Device labelling
XI. Operations and instruction manual
XII. Post-marketing plan commitments for studies

# USA/FDA Pre Market Approval System - PMA, Pre Market Notifcation - 510k, Investigational Device Exemption - IDE

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# Investigational Device Exemption – IDE

- ✓ IDE allows the investigational device to be used in a clinical study
- ✓ To collect safety and effectiveness data
- ✓ Clinical studies are most often conducted to support a PMA
- ✓ A small percentage of 510(k)s require clinical data to support the application
- ✓ It also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices
- ✓ IDE must be approved before the study is initiated

# Investigational Device Exemption – IDE

Clinical evaluation of devices that have not been cleared for marketing requires:

- ✓ an investigational plan approved by an institutional review board (IRB)
- ✓ If the study involves a significant risk device, the IDE must also be approved by FDA;
- ✓ Informed consent from all patients;
- ✓ Labeling stating that the device is for investigational use only
- ✓ Monitoring of the study and;
- ✓ Required records and reports

# Investigational Device Exemption – IDE

An approved IDE allows for:

- ✓ conducting investigations of the device
- ✓ without complying with other requirements
- ✓ that would apply to devices in commercial distribution

# Investigational Device Exemption – IDE

Also sponsors need :

- ✓ not submit a PMA or Premarket Notification 510(k)
- ✓ register their establishment, or
- ✓ list the device while it is under investigation
- ✓ are also exempt from the Quality System (QS) Regulation

NB: except for the requirements for design controls (21 CFR 820.30)

# Good Clinical Practices (GCP)

- ✓ GCP refers to the regulations and requirements that must be complied with while conducting a clinical study

- ✓ These regulations apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device :

  21 CFR 812, Investigational Device Exemptions
  21 CFR 50, Protection of Human Subjects
  21 CFR 56, Institutional Review Boards
  21 CFR 54, Financial Disclosure by Clinical Investigators

# Good Clinical Practices (GCP)

While conducting a clinical study, to ensure that the specified design requirements are met:

- ✓ procedures to control the design of the device must be implemented

21 CFR 820 Subpart C, Design Controls of the Quality System Regulation

# The clinical development of medical devices is divided into Three Stages

i. Exploratory stage:
first-in-human studies and feasibility / pilot studies,
defined as preliminary clinical

ii. Pivotal stage:
definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use

iii. Postmarket stage:
includes studies that are intended to better understand the safety of the device, including rare adverse events, and its long-term effectiveness

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## Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > How to Market Your Device > Investigational Device Exemption (IDE)

- Device Advice: Comprehensive Regulatory Assistance
- How to Market Your Device
- Investigational Device Exemption (IDE)
- Recent IDE Tracking Improvements
- IDE Approval Process
- IDE Definitions and Acronyms
- IDE Responsibilities
- IDE Application
- IDE Reports
- IDE Records
- IDE Institutional Review Boards (IRB)

# IDE Guidance

### Clinical Trials and IDE Guidance Documents

- Guidance for Sponsors, Investigators, and Institutional Review Boards – Questions and Answers on Informed Consent Elements 21 CFR 50.25(c) (PDF - 56KB)
- Acceptance of Foreign Clinical Studies
- Bioresearch Monitoring Agreement for PMAs and PDPs - February 23, 1998
- Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy (PDF Only) (PDF - 349KB)
- Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff
- Computerized Systems Used in Clinical Investigations, Guidance for Industry (PDF - 53KB)
- Continued Access to Investigational Devices During PMA Preparation and Review July 15, 1996 (Blue Book Memo) (D96-1) (Text Only)
- Guidance for Industry and FDA Staff: In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (PDF - 352KB)

# Humanitarian Device Exemption - HDE

- ✓ Device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals >> United States per year
- ✓ A device manufacturer`s R&D costs could exceed its market returns for diseases or conditions affecting small patient populations.
- ✓ The HUD provision provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations

# Clearance time frame

- Once the 510(k) is submitted to the FDA, they legally have 90 days to review it
  Entire process 4-10 months

- PMA at least 3 years, depending on clinical trials and FDA questions

- During process, they may ask for additional information at which time the "clock" is stopped and then resumed upon the FDA's receipt answers to their questions

# US market product authorization

- Device classification
- Registration and listing
- Premarket notification - 510(k)
- Premarket approval - PMA
- Humanitarian device exemption - HUD
- Investigational device exemption – IDE
- Postmarket compliance