

# **FDA WORKSHOP**

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# Objectives

- Over view of the FDA
- Review the US FDA Medical Device Regulatory Process and Device Classification
- Review FDA Quality system Regulation Requirements

# U.S Food & Administration

- Regulates Food, Drug, Device, Cosmetics
- Regulates > 1 Trillion \$ / year of US consumer goods ( 25%)
- Federal Agency under department of health & Human Service
- 9000 employees, 6 centers, 167 offices
- 20,000 Manufacturers with 80,000 products
- 15,000 audits per year

# Responsibilities of FDA

- Protect the Public Health
- Ensure the safety and Efficacy of regulated products
- Enforce the Food, Drug & Cosmetics Act and its associated acts ( 21 CFR x)

# FDA Responsibility of Radiation Emitting Products

- FDA is responsible for all radiation emitting products:
- Microwave Ovens
- Airport Baggage Scanners
- Sunlamps (Tanning Lamps)
- Laser Pointers
- X-ray unit

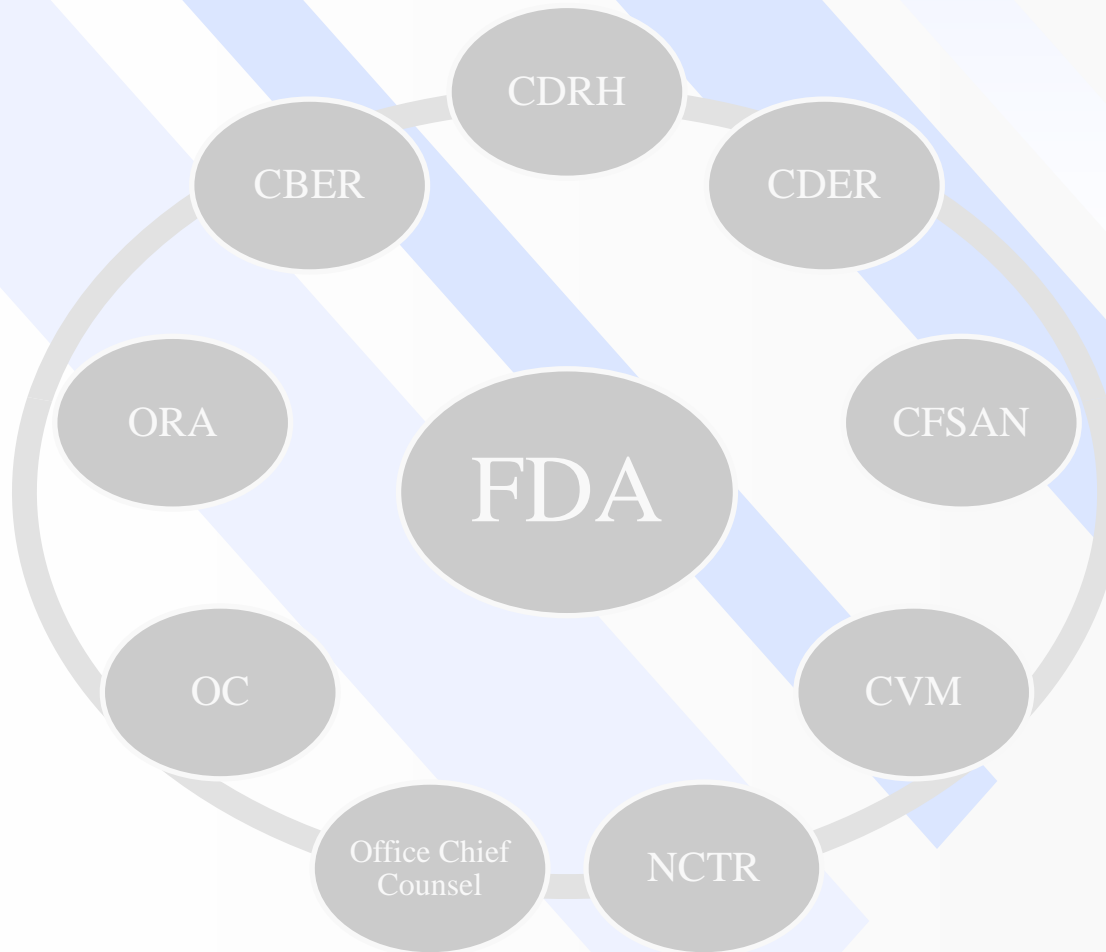
# International Responsibilities of FDA

- By law must inspect ALL Drug and Device Production Facilities IF product is sold in the US
- If inspection is Refused, then product will be Seized at Port of Entry

# Current Status of Medical Devices

- Regulated products must be produced in compliance with published quality standards
- All New drugs and most new devices must be pre-approved by FDA before commercial distribution
- Problem must be reported to FDA by users and manufacturers

# FDA Organization



# CDRH

## (Center for Devices and Radiological Health)

- Establishment, Announcement and Amendment the regulation of Medical device and
- Security of safe and effective of medical device
  - PMA (Premarket Approval), PDP (Product Development Protocol), IDE (Clinical Trials and Investigational Device Exemptions), 510(k).
  - Radiological device managing.

# Process of into market

Decide the classification of product.



Submit the requested documents.



Product and company registration.



Keep and maintain the FDA quality system Regulations

# Define the Classification

1. Search the product characteristics
2. Search the CFR title 21  
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>)
3. Check the Regulation Number
4. Decide the Regulation Number Classification
5. Submit the documents

# FDA classification

Applies to all medical devices regardless of classification, all subject to premarket and postmarket regulatory controls.

## -Classification-

-Class I: General controls

-Class II: General controls and Special controls

-Class III: General controls and PMA

# Example of Classification

- Database

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm)

Ex) Wheel chair cord

Manual type IOR 510k class I

Automatic type ITI 510k class II

-Regulation and standard

# Class I Device

- Simple, Well understood products
- Do not require any pre-market submissions to FDA-  
No prior review or approval
- Immediately to market at manufacturer's discretion

# Class II Devices

- Require special control but are substantially equivalent to product already on the market
- Require submission of a 510k and clearance to market from FDA prior to market launch
- In some cases may require clinical trials

# Class III Devices

- New device, with no equivalents in the marketplace
- FDA does not proof of safety and efficacy
- Require submission of a Pre-market Application (PMA) and approval from FDA prior to market launch

# Class III Devices (continued)

- Always require Clinical trials (After FDA approval of an Investigational Device Exemption (IDE)) to confirm safety and efficacy
- Always Require site inspections
- Multi-year process
- FDA review Fee: 259,600 USD
- 2004: 31 devices approved



# **ELECTRONIC ESTABLISHMENT REGISTRATION AND LISTING**

# What`s new in 2007

- After Oct 1 2007, all registration and listing information must be submitted electronically.
- All annual registrations must take place between Oct 01 and Dec 31 of each year.
- User fee for establishment registration for most establishment type.

# Who must register?

- Manufacturers.
- Contract manufacturers and sterilizers.
- Initial distributors/importer.
- Specification developers
- Repackagers or relabelers
- Reprocessors of single use devices.

# Who does not have to register?

- Domestic distributors of devices who do not manufacturer, repackage, process or relabel a device.
- Any person or persons importing a device that is for their personal use and not for commercial distribution.
- Refurbishers
- Component manufacturer

# When to submit registration information?

- Within 30 days after beginning.
- Within 30days after a change.
- Review and submit annually between oc 01 to Dec 31 of each year.

# Registration for Foreign Establishments.

- Same annual requirements FDA Web
- US agent information.
- Identify known initial distributor, by their registration number

# U.S agent requirement

- Any foreign establishment importing medical devices into the US
- Any one who resides or have a bussiness in the US
- Requested Information
  - 1)Name
  - 2)Address
  - 3) Telephone and Fax No.
  - 4) Email

# Basic steps for Electronic registration.

- Create an account in FURLS or use previously assigned account ID/PIN
- If first time –create account ID/PIN

# Basic steps for Electronic registration.

1

- Review or enter registration information

2

- Review edit any existing listings

3

- Certify the information is correct

# FY 2009 Fee?

- FY 2009 Fee?
- A user fee for establishment registration(initial and annual) for most establishment types in 2009
- Who must pay
  - All types of establishment want to establishment registration in FDA
- **FY 2009 Fee: 1,851 USD**

# Notice to pay a FY Fee

- Method:
  - Paid by check and sent to lock box
  - only US dollar
- Reminder: Can take up to 2weeks for CDRH to be notified of payment.

# FY FEE –exempted

- Initial distributor/ importer
- Foreign exporter-they need to register the establishment and list the device they export to US

# Listing

- Listings must be submitted at the same time as the annual registration. (Oct 1 to Dec 31)
- Encouraged to submit listings whenever there is a change. Will be immediately reflected in FURLS and on public internet the following month.

# Listing steps

1

- Complete the registration.

2

- Review listings currently on record.

3

- Check the Premarket submission needed.

- Identify the product cord.

# FDA website

- Website address:

[www.fda.gov/cdrh/reglistpage.html](http://www.fda.gov/cdrh/reglistpage.html)



# **Premarket Notification Procedures- 510K**

# What is 510(k)?

- Section 510(k) of the Food, Drug & Cosmetics Act for **device approval process**
- Premarket Notification
- Marketing Clearance for commercial distribution
- 21 CFR 807 Subpart E (Premarket Notification Procedures)
- Clears a medical device for commercial distribution via **“Substantial Equivalence”**
- **k-xxxxxx number (SE Letter)**

# 510(k) Required Medical Devices

- Class I & Class II Medical Devices
- Predicate devices is needed for substantial equivalence comparison.
- 510(k) Submission
- What is a Predicate Device?
  - Medical devices already cleared by FDA for commercial distribution
  - Medical devices similar in performance and indication for use.

# Request for 510k submission

- ◆ FDA Guidance

FDA has divided the medical product according to Code Of Federal Regulation and proposal the guidance of 510(k)

- ◆ Evaluation and approval independently as national organization, reject the un-adquated documentation

- ◆ After submit the documents FDA will be given the additional request such as test or other information through the review.

# Substantial Equivalence

- Once a medical device is determined to be substantially equivalent to the predicate device, FDA issues “SE Letter” and then, the medical device may be distributed for commercial use in the U.S.
- If FDA determines a medical device is not substantially equivalent, FDA sends “NSE Letter” to the applicant.
- Manufacturer is not allowed to sell the medical devices before it receives SE letter from FDA.

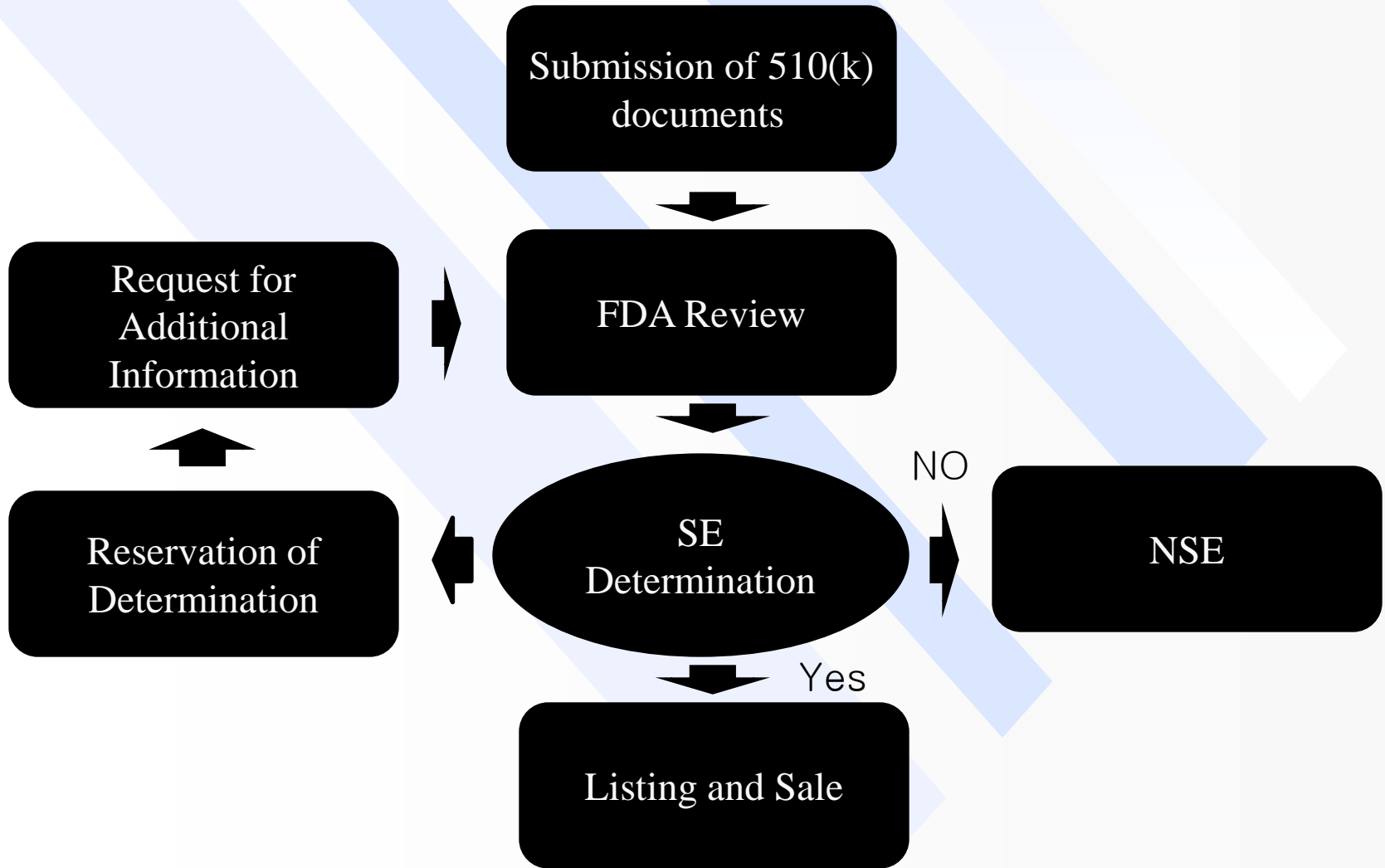
# Who is required to submit 510(k)

- U.S. Manufacturer
- Specification Developer
- Repacker or Relabeler
- Foreign Manufacturer/Exporter
- U.S. representative of foreign manufacturer/exporter

# Device Exempt from 510k

- Unfinished Device
- Finished device not sold in US
- Device covered under another 510(k)
- Preamendment device
- Custom device
- Veterinary Device

# 510(k) Procedure



# Information requested in 510k (21 CFR 807.87)

- Submitter`s name, address, phone/fax, contract person
- Device classification name, regulation number, device class.
- Common/usual name and trade/proprietary name and model number.
- Identification of marketed device to which equivalence is claimed.

# Information requested in 510k (21 CFR 807.87)

- Copy of Medical device user Fee Cover sheet
- CDRH Premarket review submission cover sheet
- Indication for use statement
- Truthful and Accurate statement
- Labeling

# Technical document request

- Picture, engineering drawings
- Performance Data(bench, animal, clinical)
- Sterilization, Software information
- Address information requested in specific guidance documents
- Standards Data Report (FDA form 3654)
- If 510(k) has clinical trial (FDA form 3674)

# General Document List for 510(k) Submission

- 1. Medical Device User Fee Cover Sheet
- 2. CDRH PMA Cover sheet
- 3. 510(k) Cover Letter
- 4. Indication for Use
- 5. 510(k) Summary or Statement
- 6. Truthful and accurate statement
- 7. Safety and Effectiveness Statement
- 8. Label and Package
- 9. User Manual
- 10. Product Description
- 11. Substantial Equivalence Report
- 12. Clinical Data
- 13. Test Reports

# When FDA requests additional information

- Incomplete application (reject application)
- Test reports are required to prove substantial equivalence
- Review Period: 90 days (working day)
- Additional information should be submitted within 30 days
- Deadline can be extended by written request (up to 6 months)
- Deadline cannot be extended via FAX or email

# 510k submission fee (FY 2010)

- 510k Submission fee: 4,007 USD
- Small business : 2,004 USD
  - Qualification: less than 1 billion US dollar

# FDA common request

- All establishment should be complied with:
- Quality system Regulation (QSR)
- Establishment Registration with FDA for every facility, Renew Annually
- Device Listing with FDA listing All devices produced, Renew Annually

# 510K submission

- Traditional 510k
- Special 510k
- Abbreviated 510k

# Traditional 510k

- Most of case of 510k.
- New product of manufacturer where try to 510k.
- Can not applied a Special and Abbreviated 510k
- Change the intend use or any technology.

# Special 510k

- Manufacture Modifies won legally marketed class I, II, or III device & determines that a 510k is required.
- Modification does not affect intended use or fundamental scientific technology.

# Special 510k

- Applied the satisfactory report form where is the manufacturer already in market to sale
  - 1) Case to has experience to 510k submission.
  - 2) Medical device which has revised and improved
  - 3) No changed the intended use of Medical device.

# Special 510k contents

- Cover sheet: Special 510k Device
- Name of marketed device and 510k No.
- SE report
- Intended use
- Labelling
- Summary of Design control

# Special 510k process

- Cover letter and cover sheet

- Declaration of Conformity

- 30 days review

# Special 510k

- Can not be a special
- Cannot declare conformity with design controls
- Change in Intended use
- Change is fundamental scientific technology.

# Abbreviated 510k

- Device is subject to Special controls.
- FDA guidance or recognized standard.
- Manufacturer can be submit the adequate evidence follow FDA special controls.

# Abbreviated 510 cont

- Manufacture must have supporting data at time of 510k submission.
- Submit the declaration of conformity to a recognized standard.
- Submit the statement that the product will conform to a recognized standard when finally marketed.
- Submit the statement that the product will conform to a no-recognized standard-decided case by case.

**Deciding when to submit a  
510k for a change to an existing  
device.**

# Modifications that do not require a 510k

- Addition of a trade name
- Additional sizes within the specifications.
- Change from one traditional sterilization to another.
- Deleting indications.

# Modifications that do not require a 510k (cont)

- Examples of labeling changes that generally do not require a new 510k notice.
- Changing the warnings or precautions or revising the labeling to clarify the instruction for use.

# Modified that require a new 510k

- Request a New 510k with modified labelling
  - Expanding the indication for use
  - Switching from prescription to OTC.
  - Deleting a contraindication-Deleting contraindicated for pediatric use.

# **Technology, Engineering and Performance changes.**

-Evaluated and validated according to GMP requirements to determine if a new 510k notice must be filed.

# Technology, Engineering and Performance changes (cont.)

- Require a New 510k
  - Changing Control mechanism (analog>>Digital)
  - Changing the operating principle.
  - Changing the energy source.
  - Changing the sterilization procedure in a manner that affects performance specifications or reduces the sterility assurance level.

# Technology, Engineering and Performance changes (cont.)

- Do not require a New 510k
  - They do not affect the indication for use.
  - they do not require supporting clinical data on Safety & Effectiveness for purposed of determining substantial equivalence.
  - The result of design validation do not raise new issues of S& E.

# Material Change

- Require a New 510k
  - Changes in the basic type of material or the material formulation.
  - Differ for implantable devices and non-implantable device.

# Material change (cont.)

- The new material is likely to contact body fluids or tissues must submit a New 510k

# Material change (cont.)

- For non-implantable devices, a new 510k generally should be submitted if
  - The new material is likely to contact body fluids or tissues
  - new biocompatibility test required.
  - In determining whether a ne 510k must be submitted, manufacturers also should consider whether the change in materials alters the performance specification for the device.

# Material change (cont.)

- Do not require a New 510k
  - Change the supplier of raw material.

# 513g request

- When unsure of how a device is classified, regulated.

# 513g request

- Information needed in letter.
  - MUDFMA Coversheet
  - Coverletter indicating it is for requesting device classification & regulatory requirements.
  - Contact person`s name, address, phone No, Fax No.
  - Detailed device description
  - Indication for use.
  - Labeling.

# 510k Third party review

- Third party review program
- Gives manufacturers the option of using accredited, non-Federal organizations to review 510k.

# Third party review

- Possessiveness
  - Usually more timely
  - Many Aps also have standards and foreign regulatory expertise.
- Negativeness
  - Can not be applied Class III and Class II(Implantable)
  - More payable

# 510k exempted.

- Laser product needed to documents.
- Accession Number
- Annual Report

# FDA Accession number?

- FDA Accession number is given to radiological device such as a laser/ultrasound/ionization device which is need to sale in US market by FDA CDRH.
- Mobile phone, TV, Monitor, X-ray diagnosis machine and laser products.

# Annual Report?

- Manufacturer should be submitted an annual report which is applied safety and effectiveness to FDA.

# US agent

- Contact in US territory.
- Contact between FDA and Manufacturer.
- Answering the request of product and informed scheduled audit by FDA.

# FDA Quality system regulations

# FDA Quality Regulations

- Found in the code of Federal Regulation
- 21 CFR 820 – Quality system regulations (formerly Good manufacturing Practices – GMPs)
- -Regulations for the development, manufacturer, distribution and tracking of medical devices

# Elements of the FDA quality system Regulations

- Harmonized with ISO 13485
- -Documented program
- -Management Responsibility
- -Validated systems
- -Sourcing and manufacturing controls
- -Corrective Action/ Prevention Action
- -Complaint Handling
- -Training

# Major difference between FDA Regulation and ISO 13485

- FDA does not care about Customer Satisfaction
- Only concern is health and safety of the public
- No product optimization (except to reduce defects)
- No economic improvement
- No internal customer
- No market share concerns



THANK YOU