



# Regulatory Clearance to Market EC and US

George Buchan

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# We Are In Business To:

- Provide innovative consulting, training and support services that deliver value to our Clients products and enterprises.
- Engage and partner with experienced, professional associates and organisations to deliver a broad range of practical services to the medical device sector.
- Develop and apply our expertise with diligence, consideration, enthusiasm, openness and integrity.
- Deliver what we promise to ensure Client satisfaction.
- Maintain ethical standards of professional conduct.
- Remain profitable to invest and grow.

# Consultancy / Training Services

## ■ Quality Assurance

- Management Systems (ISO13485:2003, CFR820, CMDCAS)
- Supply Chain Management

## ■ Regulatory Affairs

- CE marking
- FDA Applications / Clearance
- Canadian Licensing
- Other Country Licensing: Japan, China, Taiwan, Australia.

## ■ Outsourced Services

- Technical Documentation (Design Dossier) Design History File, Device Master File Compilation & Submission
- Auditing
- Regulatory Affairs / Quality Assurance Executive

# PERCEPTIONS

- **Need to Change current perception:**
  - **“Medical device regulation is a nightmare”**
- **To:**
  - **Understanding and Applying Regulation & supporting Standards / Guidelines to improve:**
    - **Knowledge of market, competitive devices & Clinical Need**
    - **Concept-Market Lead Time**
    - **Device Specification, Design & Development**
    - **Supply Chain Control**
    - **Device Presentation & Safety In Use**
    - **Distribution control**
    - **Awareness of device performance in use**

# MEDICAL DEVICES IN EUROPE

- **Community legal framework for medical devices:**
  - **Medical Devices Directive (MDD)**
  - **Active Implantable Medical Devices Directive (AIMDD)**
  - **In Vitro Diagnostic Directive (IVDD)**
- **These Directives must be transposed into national law.**
  - **Note:** Each member state does this differently

# Medical Devices Directive

- Council Directive 93/42/EEC of 14 June 1993

- Amended by:

- Directive 98/79/EC of 27 Oct 1998
- Directive 2000/70/EC of 16 Nov 2000
- Directive 2001/104/EC of 7 Dec 2001
- Regulation (EC) No 1882/2003 of 29 Sep 2003
- Directive 2007/47/EC of 5 Sep 2007

- Contains:

- 23 Articles & 12 Annexes

# EC Regulatory Environment:

## ■ Competent Authorities:

- Each Member state will appoint a Competent Authority for all medical devices
- MHRA (Medicines & Healthcare products Regulatory Agency) is the Competent Authority in UK

## ■ Notified Bodies:

- Inspection & Testing of Products
- Assessment of Manufacturing & Sterilisation Validations
- Assessment of manufacturers compliance with Standards
- Approval / Issue of their Notified Body CE Number via the EC Certificate

# 10 KEY STEPS TO REGULATORY CLEARANCE

1. **Establish your Device is a Medical Device:**
  - **For EC: Establish what Directive Applies and the supporting Harmonised Standards / Guidelines.**
  - **For US: Establish what regulation applies, the predicates, guidelines or special controls to be exercised & Standards to be met.**
2. **Define the device Indications for Use & Performance Claims to be made:**
  - **For EC: These are defined by Manufacturer**
  - **For US: Compare Identification Section of Regulation with Predicate Claims (510k Summaries).**
3. **Classify your device:**
  - **For EC: See ANNEX IX of the MDD**
  - **For US: See Classification Database / Regulation**
4. **Select the Conformity Route:**
  - **For EC: See Selection Charts (If NB prepare application / obtain quotations)**
  - **For US: See Classification Database / Regulation**
5. **Define who does what: Contract Out?**

# 10 KEY STEPS TO REGULATORY CLEARANCE

6. Prepare a clear development plan & include regulatory requirements.
7. Document and implement systems of control (Design – Post Market Surveillance).
8. Develop Technical Agreements with Suppliers / Contractors.
9. Collate evidence:
  - For EC: Technical Documentation including the Essential Requirements, Harmonised Standards fulfillment during the design, development and manufacturing stages and Clinical Evaluation.
  - For US: Similar to EC, however assessment must be against Predicates & evidence compliance with US Recognised Standards and Performance Standards.
10. Regulatory Application:
  - For EC: Self Declare for Class I. For other Classes agree with Notified Body the assessment date.
  - For US: Submit the 510k Application to the FDA.

# STEP 1 : IS MY DEVICE A MEDICAL DEVICE

## ■ Definition: “Medical Device”

- any instrument, apparatus, software, appliance, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease.
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,
- and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

# STEP 2 : INTENDED USE & CLAIMS

## ■ Definition: “Intended Purpose”

- the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.
- Note: The EC Intended Purpose + Claims embrace the US “Intended Use” Statement & “Indications for Use” Statements

## ■ File in Technical Documentation

# STEP 3: EC CLASSIFICATION

## ■ Classification Rules Annex IX

- **Devices must be classified into:**
  - **Class I : Low Risk**
    - This is further split into:
      - » Class I Sterile and
      - » Class I Measuring Device
  - **Class II a: Medium Risk**
  - **Class II b: Medium Risk**
  - **Class III: High Risk**

# STEP 3: EC CLASSIFICATION

## ■ Classification Rules Annex IX

- **Non-invasive**
  - Rules 1- 4
- **Invasive**
  - Rules 5 - 8
- **Active**
  - Rules 9 - 12

# STEP 3: EC CLASSIFICATION

## ■ Classification Rules Annex IX

### ● Special Rules:

**13.** Devices incorporating Medicinal Product

**14.** Devices for Contraception or prevention of STD

**15.** Devices for:

- » Disinfecting, cleaning, rinsing or hydrating contact lenses.
- » Disinfecting Medical Devices.

**16.** Non-active devices intended for the recording of X-Ray Diagnostic Images

**17.** Devices utilising animal tissues

**18.** Blood Bags

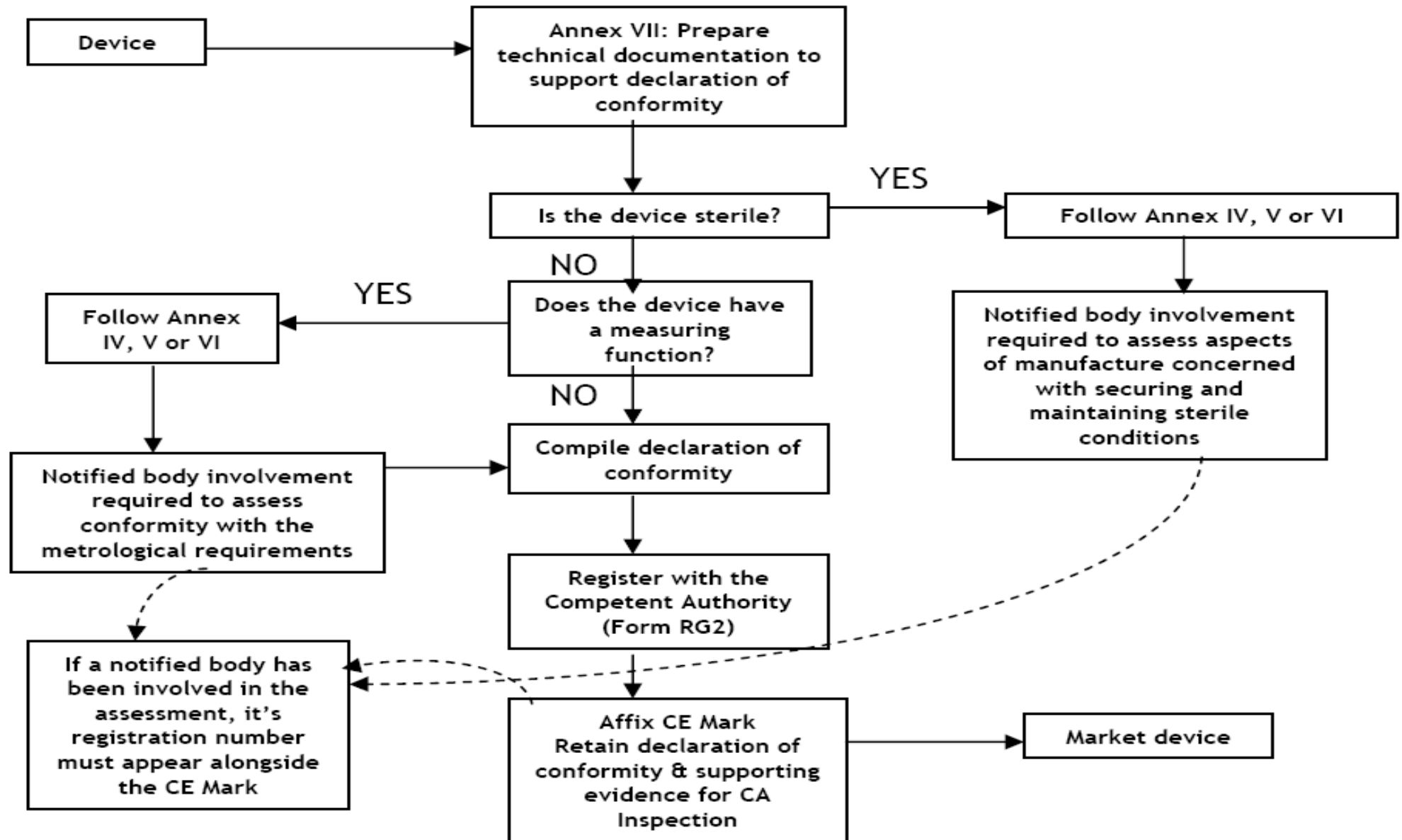
## ■ File in Technical Documentation



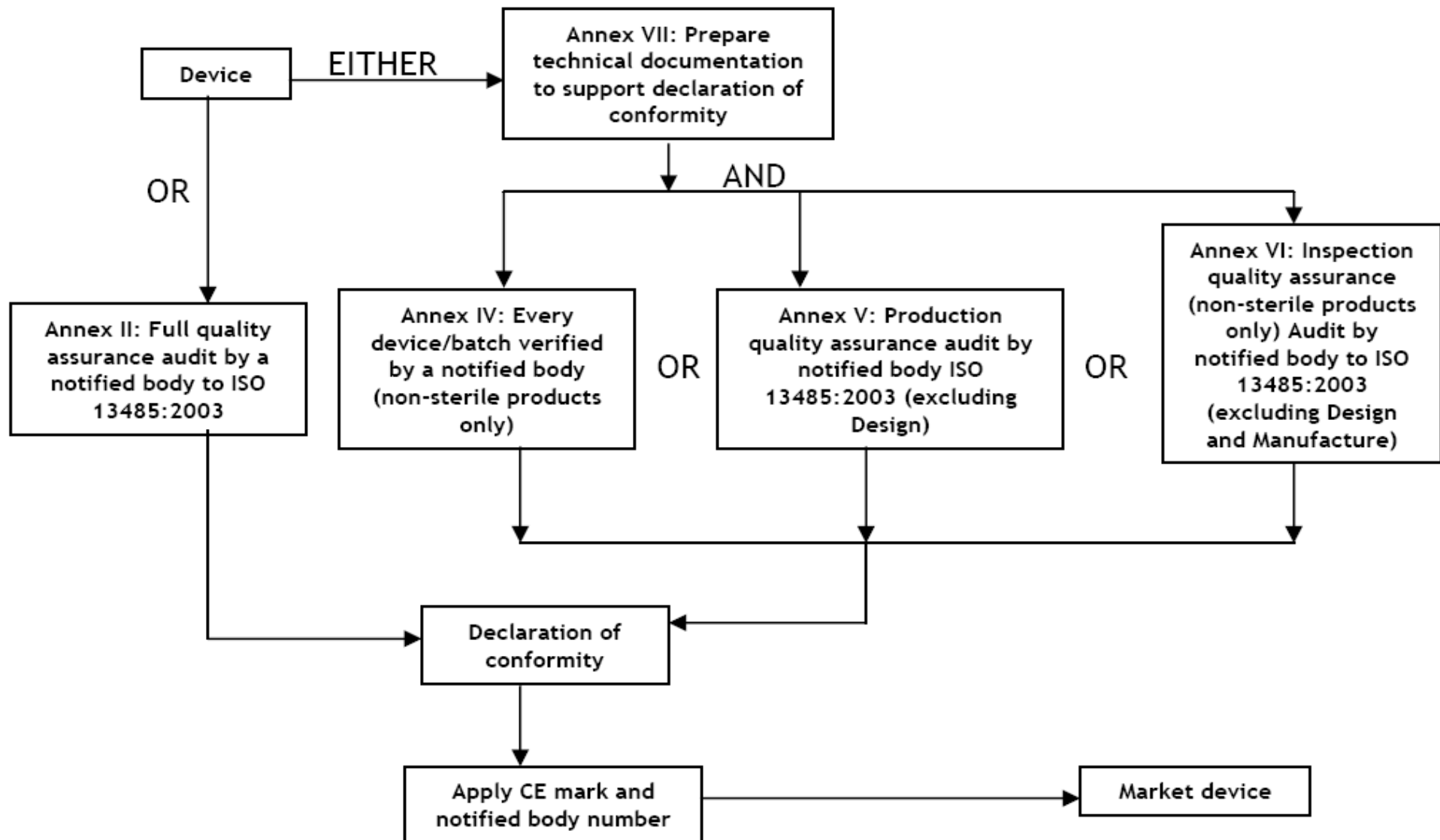
## **STEP 4: EC COMPLIANCE ROUTES**

**File Route Selected in Technical Documentation**

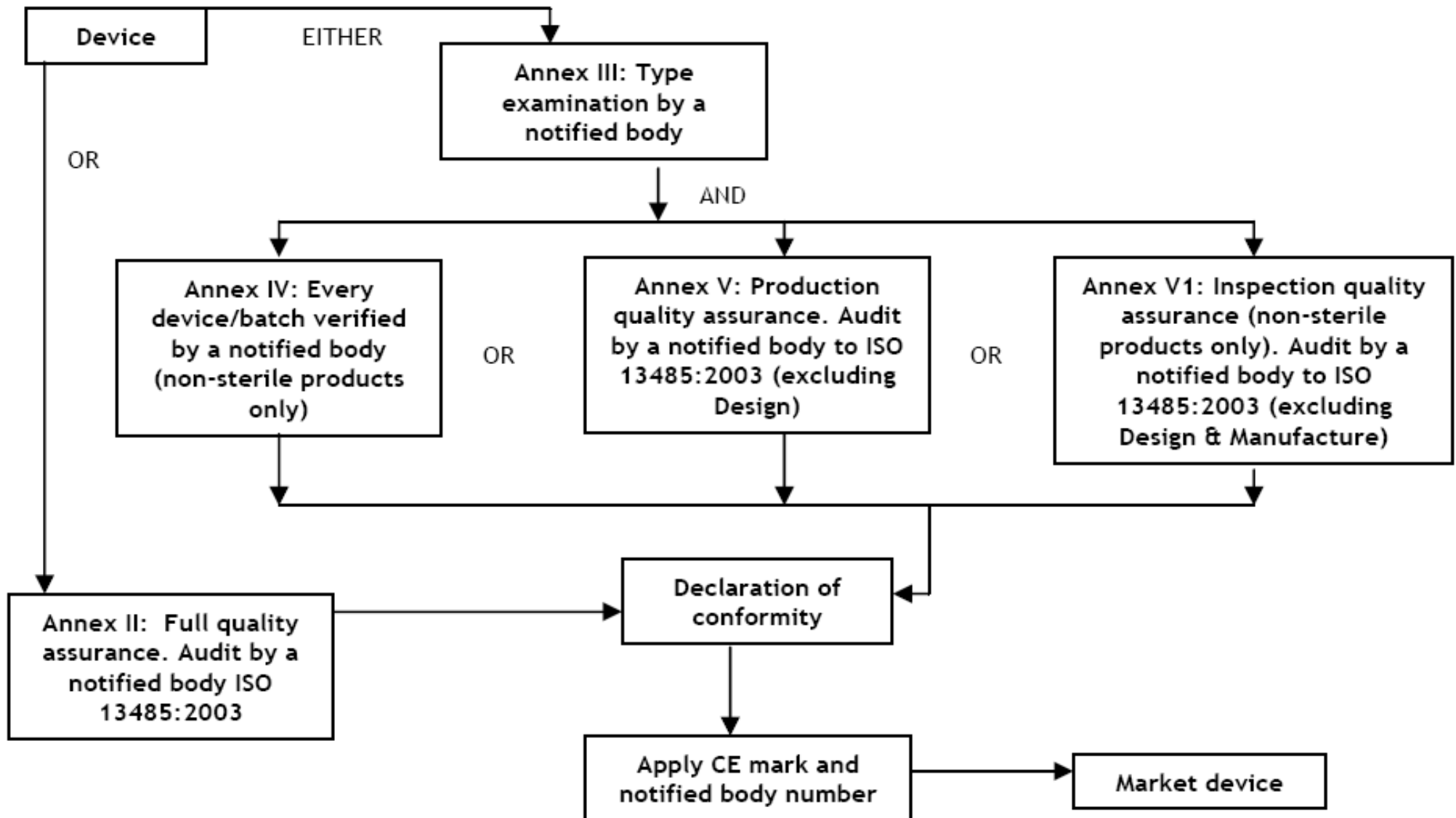
# CLASS I MEDICAL DEVICES - CE MARKING ROUTES



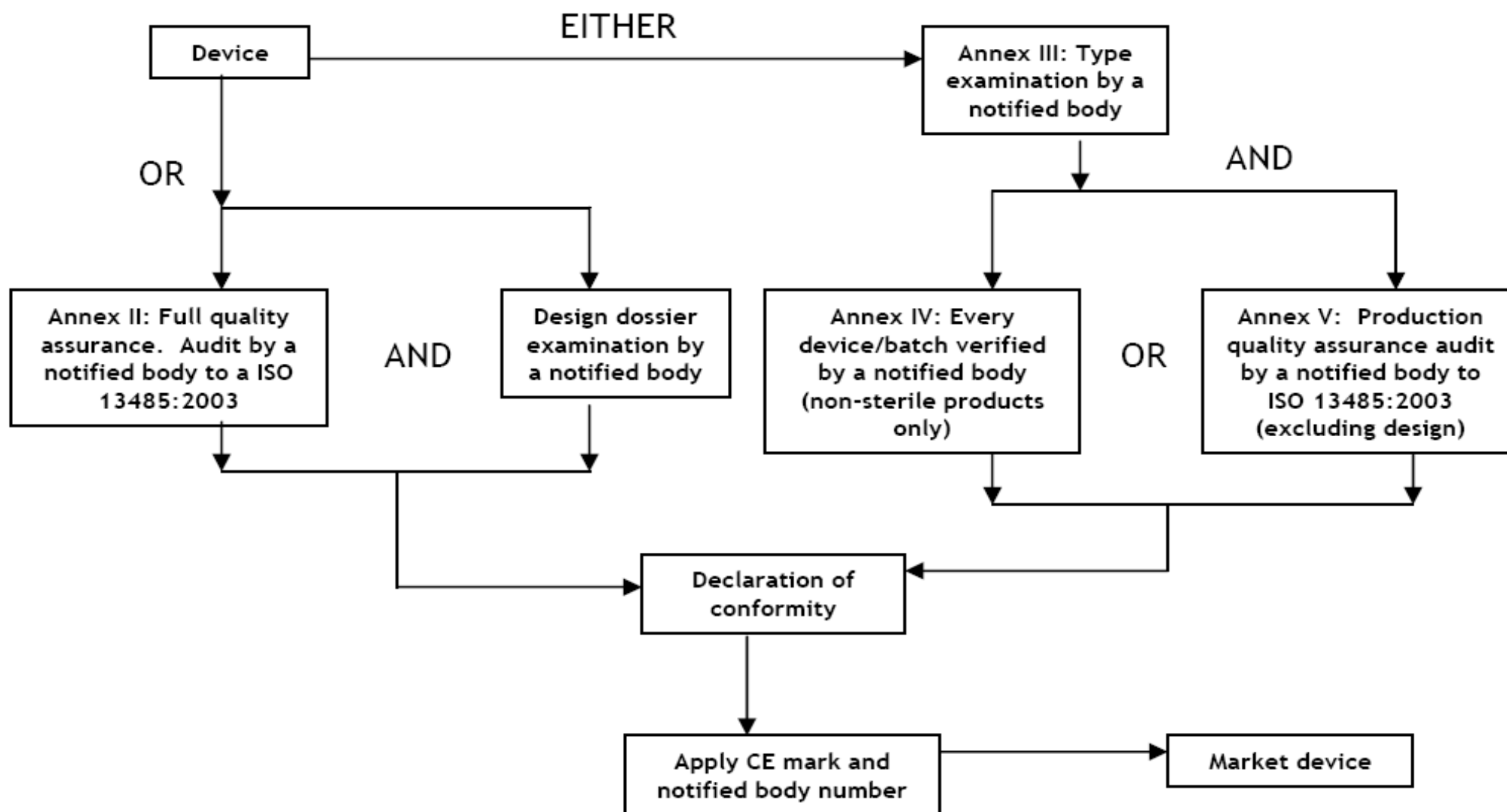
## CLASS IIa MEDICAL DEVICES - CE MARKING ROUTES



# CLASS IIB MEDICAL DEVICES - CE MARKING ROUTES



# CLASS III MEDICAL DEVICES - CE MARKING ROUTES



# STEP 5: WHO DOES WHAT?

## ■ Establish:

- Who is the manufacturer?
- Who is supplying Specifications? (How robust are they?)
- Who is Designing & Where?
- Who is Supplying Materials / Components?
- Who is Assembling / Manufacturing & Where?
- Who is Packing / Labelling & Where?
- Who is Distributing / Installing / Maintaining & Where?
- Are Technical Agreements required?
- Are Distributor / Maintenance Agreements required?
- Who collates the Technical Documentation?
- Who is responsible for & Where is the Technical Documentation stored?

## ■ Define in Technical Documentation

# STEP 6: PLANNING

- Establish clear Plan(s) with timescales / milestones & defined responsibilities for:
  - Documenting Systems of control
  - Collating Clinical Data
  - Materials Selection & Testing
  - Device Design
  - Prototyping + Testing
  - Device Verification & Validation
  - Design Transfer to Manufacture
  - Process Definition & Validation
  - Packaging
  - Labelling
  - Final Device Testing
  - Testing Vst Predicates
  - Clinical Evaluation
  - Collation of Technical Documentation
- Conduct Reviews & Document
- File Evidence in Technical Documentation

# STEP 7: SYSTEMS OF CONTROL

- Define, Document and Implement systems of control for elements such as:
  - Design
  - Engineering / Specification Change Control
  - CE Compliance (can include US / Canada et al)
  - Document Control
  - Record Control
  - Control of Contractors / Suppliers
  - Manufacturing Control
  - Process Validation
  - Packaging Control
  - Labelling Control
  - Environmental control
  - Sterilisation Control
  - Release Control
  - Post Market Surveillance & Vigilance
- Use ISO 13485:2003, CFR 820 QS Regulation & CMDCAS as guide

# STEP 8: TECHNICAL AGREEMENTS

- **Establish Technical Agreements with Key Contractors / Suppliers that will define:**
  - **Scope of Activities**
  - **Term & Termination**
  - **IP**
  - **Confidentiality**
  - **Responsibilities of Contractor**
  - **Responsibilities of the Client**
  - **Standards / Specifications to be met**
  - **Process Controls & Traceability Requirements**
  - **Record Retention**
  - **Right of access for Inspectors / Regulators**
  - **Control of Changes**
- **File Agreements in Technical Documentation**

# STEP 9: COLLATE THE EVIDENCE

## ■ GENERAL REQUIREMENTS

- **Devices to be Designed to:**
  - Reduce Risk of Error in Use
  - Conform to Safety Principles:
    - eliminate or reduce risks as far as possible (inherently safe design and construction),
    - where appropriate take adequate protection measures including alarms if necessary,
    - in relation to risks that cannot be eliminated, inform users of the residual risks due to any shortcomings of the protection measures adopted.
- **Achieve the performances intended and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions as specified by the manufacturer**
- **Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.**
- **Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.**

## ■ File Evidence in Technical Documentation

# STEP 9: COLLATE THE EVIDENCE

## ■ GENERAL REQUIREMENTS

- **Characteristics and performances must not be adversely affected:**
  - to compromise the clinical conditions and safety of the patients and, where applicable, of other persons during:
    - the lifetime of the device as indicated by the manufacturer, when
    - the device is subjected to the stresses which can occur during normal conditions of use.
  - during transport and storage taking account of the instructions and information provided by the manufacturer.

## ■ File Evidence in Technical Documentation

# STEP 9: COLLATE THE EVIDENCE

## ■ Design & Construction Requirements

- Chemical, physical & biological properties
- Infection & microbial contamination
- Construction & environmental properties
- Devices with a measuring function
- Protection against radiation
- Requirements for devices connected to or equipped with an energy source
  - Protection against electrical risks
  - Protections against mechanical and thermal risks
  - Protection against the risks posed to the patient by energy supplies or substances
- Information Supplied by the Manufacturer
  - Installation Instructions, User Instructions, Patient Instructions, Calibration Instructions
  - Label on device, pouch / primary pack, secondary pack / sales pack & box.

## ■ File Evidence in Technical Documentation

# STEP 9: COLLATE THE EVIDENCE

- **Compliance with Standards**
  - **EC Harmonised Standards**
  - **International Standards**
  - **US Performance Standards**
- **Comparative Data**
  - **Predicates (for US 510k)**
- **Clinical Evaluation**
  - **Publications**
  - **Modelling / Bench Tests**
  - **Animal Studies**
  - **Clinical Investigations**
- **File Evidence in Technical Documentation**

# STEP 9: COLLATE THE EVIDENCE

- Define Hazards & Assess Risks to Patient & Users arising from:
  - Design
  - Software
  - Materials
  - Process(s) of Manufacture
  - Packaging / Storage
  - Labelling / Information Supplied
  - Installation / Repair / Update
  - Clinical Use / Application
  - Shelf Life / Storage
  - Lifetime of Device
- File Evidence in Technical Documentation

# STEP 9: COLLATE THE EVIDENCE

- COMPLETE TECHNICAL DOCUMENTATION
- USE STED as a basis see later

# STEP 10: EC DECLARATION OF CONFORMITY

## ■ For Class I Devices Self Declare

- There is a charge of £70 per registration or change of registration.
- The regulations require this fee to accompany the information when it is sent to MHRA
- Complete Registration forms:
  - RG2 (for medical devices)
  - RG3 (for in vitro diagnostic medical devices)

## ■ For Class I Sterile or Measuring and for Class II and Class III devices

- Notified body will assess in accordance with the conformity route selected.
- Notified Body provides EC Certificate to permit marketing of device.

# CE MARK: Medical Devices

- Confirms that the product meets the Essential Requirements of the Directive.
- The CE Mark should be on the product or on the label and in the IFU.
- Exclusions:
  - Custom Made Devices
  - Devices used in clinical trials
  - Demonstration devices e.g. trade show
  - Procedure Packs





# USA REGULATORY FRAMEWORK

MEDICAL DEVICES

# FDA REGULATION

## ■ FEDERAL FOOD, DRUG & COSMETIC ACT

- 800: General
- 801: Labelling
- 803: Medical device reporting
- 806: Medical devices; reports of corrections and removals
- 807: Establishment registration and device listing for manufacturers and initial importers of devices
- 808: Exemptions from Federal pre-emption of State and local medical device requirements
- 809: In vitro diagnostic products for human use
- 810: Medical device recall authority
- 812: Investigational device exemptions
- 813: [Reserved]

# FDA REGULATION

## ■ FEDERAL FOOD, DRUG & COSMETIC ACT

- 814: Premarket approval of medical devices
- 820: Quality system regulation
- 821: Medical device tracking requirements
- 860: Medical device classification procedures
- 861: Procedures for performance standards development
- *862: Clinical chemistry and clinical toxicology devices*
- *864: Haematology and pathology devices*
- *866: Immunology and microbiology devices*
- *868: Anaesthesiology devices*
- *870: Cardiovascular devices*
- *872: Dental devices*

# FDA REGULATION

## ■ FEDERAL FOOD, DRUG & COSMETIC ACT

- *874: Ear, nose, and throat devices*
- *876: Gastroenterology-urology devices*
- *878: General and plastic surgery devices*
- *880: General hospital and personal use devices*
- *882: Neurological devices*
- *884: Obstetrical and gynaecological devices*
- *886: Ophthalmic devices*
- *888: Orthopaedic devices*
- *890: Physical medicine devices*
- *892: Radiology devices*
- **895: Banned devices**

# STEP 1: US DEFINITIONS

## ■ Definition

- Is your device a medical device?
- Is your product regulated by a department in the FDA other than the Center for Devices and Radiological Health (CDRH) and for which there are different provisions in the FD&C Act?
  - Human Drug Products
  - Biological Products
  - Animal Drugs and Devices
  - Food Products and Cosmetics
- Or your product may be a medical device and is also an electronic radiation emitting product with additional requirements.

# STEP 1: US DEFINITIONS

- “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 USP, 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 any of 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.”

# STEP 1: US DEFINITIONS

## ■ Definition “Electronic product”

- (A) any manufactured or assembled product which, when in operation,
  - (i) contains or acts as part of an electronic circuit and
  - (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
- (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation

# US DEVICE CLASSIFICATION

## ■ FEDERAL FOOD, DRUG & COSMETIC ACT

- **FDA must classify devices into:**
  - Class I
  - Class II
  - Class III
- **Classification is determined by the amount of regulation necessary to provide a reasonable assurance of safety & effectiveness.**
- **File justification in Technical Documentation**

# STEP 2-3 IFU & Classification: RADIOLOGY DEVICE

- Picture archiving and communications system. (CFR 892.2050)
  - **Identification.**
    - A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.
  - **Classification.**
    - Class II (special controls); voluntary standards--Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).1270: Human tissue intended for transplantation

# STEP 2-3 IFU & Classification: GASTROENTEROLOGY- UROLOGY DEVICE

- Ingestible telemetric gastrointestinal capsule imaging system (CFR 876.1300)
  - **Identification.**
    - An ingestible telemetric gastrointestinal capsule imaging system is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.
  - **Classification.**
    - Class II (special controls). The special control is FDA's guidance, "Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging Systems; Final Guidance for Industry and FDA."

# STEP 2-3 IFU & Classification: ORTHOPEDIC DEVICE

- Resorbable calcium salt bone void filler device (CFR 888.3045)
  - **Identification.**
    - A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.
  - **Classification.**
    - Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA."

# STEP 2-3 IFU & Classification: GASTROENTEROLOGY- UROLOGY DEVICE

- **Nonimplanted electrical continence device (CFR 876.5320)**
  - **Identification.**
    - A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (884.5940).
  - **Classification.**
    - Class II (performance standards).

# STEP 2-3 IFU & Classification: GENERAL & PLASTIC SURGERY DEVICE

## ■ Surgical mesh (CFR 878.3300)

### • Identification.

- Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery.

### • Classification.

- Class II

### • Guidance

- Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final

# STEP 2-3 IFU & Classification: OBSTETRICAL & GYNECOLOGICAL DEVICE

- **Contraceptive Tubal Occlusion Device (TOD) and introducer (CFR 884.5380)**
  - **Identification.**
    - A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure, e.g., a band or clip on the outside of the fallopian tube or a plug or valve on the inside. The devices are used to prevent pregnancy.
  - **Classification.**
    - Class III (premarket approval).

# STEP 2-3 IFU & Classification: OPHTHALMIC DEVICE

## ■ Keratome (CFR 886.4370)

### • Identification.

- A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

### • Classification.

- Class I

### • Guidance

- Guidance for Industry and FDA Staff - Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions

# STEP 4: SELECT US CONFORMITY ROUTE

## ■ FDA has two lists:

- **Generic list of devices exempt from pre-market notification:**
  - most Class I devices and
  - some Class II devices.
- **List of devices that fit the reserved criteria of 510(l).**
  - This reserved criteria means a pre-market notification 510(k) submission.

# STEP 4: SELECT US CONFORMITY ROUTE

- For Class I Devices the FDA requires pre-market notification if device:
  - Has an intended use different from that of the legally marketed device in that generic type.
  - Operates using a different fundamental technology.
  - Is an In-vitro device.

# STEP 4: SELECT US CONFORMITY ROUTE

## ■ Exemption for 510(k)

- FDA provides a list of Class II devices that do not require the submission of a pre-market notification 510(k).
- The list details limitations on exemptions.

## ■ Additional Exemptions

- Under 510(m) (2) of the Act any interested person may request exemption from pre-market notification requirements. Request should:
  - Identify generic type of device by CFR section number.
  - Include statement of justification.
  - Detail why pre-market notification is unnecessary to provide reasonable assurance of the safety & effectiveness of the device.

## ■ File Evidence in Technical Documentation

# STEP 4: 510k US CONFORMITY ROUTE

- A 510(k) is a premarketing submission made to FDA to demonstrate:
  - the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).

# STEP 4: 510k US CONFORMITY ROUTE

## ■ SUBSTANTIAL EQUIVALENCE

- SE means that the new device is as safe and effective as the predicate device(s).
- A device is SE if, in comparison to a predicate device it:
  - has the same intended use as the predicate device; AND
  - has the same technological characteristics as the predicate device OR
  - has the same intended use as the predicate device; 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 as safe and effective as the predicate device.

# STEP 4: 510k US CONFORMITY ROUTE

- A claim of SE does not mean the new and predicate devices must be identical.
- SE is established with respect to:
  - intended use,
  - design,
  - energy used or delivered,
  - materials,
  - performance, safety, effectiveness,
  - labelling,
  - biocompatibility,
  - standards, and
  - other applicable characteristics.
- File Evidence in Technical Documentation

# STEP 9: COLLATE EVIDENCE

## ■ Select the Appropriate Marketing Application

- Collate and / or develop the data and/or information necessary to submit a marketing application, and to obtain FDA clearance to market.
- For some [510(k)] submissions and certainly for most PMA applications, clinical performance data is required to obtain clearance to market.
  - In these cases, conduct of the trial must be in accord with FDA's Investigational Device Exemption (IDE) regulation, in addition to marketing clearance.

# STEP 9: COLLATE EVIDENCE

- **Data required for US Regulatory Submission including:**
  - **Design History File**
  - **Device Master Record**
- **Can use Sted as basis for Technical Documentation**

# STEP 10: US REGULATORY APPLICATION

## ■ 510 K APPLICATION Traditional Format or use STED

- **Name of device**
  - trade or proprietary name, if any, and the common or usual name or classification name of the device.
- **Classification of the device**
  - appropriate panel (e.g. cardiovascular, dental, etc.), and product code, if known.
- **Description of the device**
  - include device specifications
  - reference applicable guidance documents, special controls, or standards;
  - photographs or engineering drawings should be supplied, if applicable
- **Comparison with a predicate device(s)**
  - indicating similarities and/or differences accompanied by comparative data
  - identification of materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
- **Intended use of the device**
- **Proposed label, labeling, and advertisements for the device and directions for use.**
- **Information on:**
  - sterilization, biocompatibility, expiration date, etc., if applicable.

# GHTF: STED (Summary Technical Documentation)

## 1.0 Device Description and Product Specification, Including Variants and Accessories

### 1.1 Device Description

### 1.2 Product Specification

### 1.3 Reference to similar and previous generations of the device

## 2.0 Labelling

## 3.0 Design and Manufacturing Information

### 3.1 Device Design

### 3.2 Manufacturing Processes

### 3.3 Design and Manufacturing Sites

## 4.0 Essential Principles (EP) Checklist

## 5.0 Risk Analysis and Control Summary

## 6.0 Product Verification and Validation

### 6.1 General

### 6.2 Biocompatibility

### 6.3 Medicinal Substances

### 6.4 Biological Safety

### 6.5 Sterilisation

### 6.6 Software Verification and Validation

### 6.7 Animal Studies

### 6.8 Clinical Evidence

## 7.0 Declaration of Conformity

## Appendices

# FDA FEES

APPLICATION	STANDARD FEE	SMALL BUSINESS FEE
PRE-MARKET NOTIFICATION	\$3,404	\$1,702 (if T/o <\$100M pa)
PRE-MARKET APPLICATION	\$185,000	\$46,250 (No fee for first application if T/o <\$30M pa)

## ■ Exemptions from Fee

- **Devices solely for paediatric use**

# FDA: OTHER CONSIDERATIONS

## ■ Pre-market Requirements:

- Labelling Regulation
- Registration / Listing Regulation
- US Agent Appointment
- Quality System Regulation

## ■ Post-market Requirements:

- Medical Device Reporting

## ■ FDA can order postmarket surveillance for any Class II and Class III device.