

# **Office of Device Evaluation (ODE)**

## *Examples of the Medical Device Types Reviewed by Each Division*

### **Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices (DAGRID)**

#### **Anesthesiology Devices Branch (ADB)**

- Anesthetic catheters
- Hyperbaric chambers
- Oximeters
- Airway monitoring systems
- Gas analyzers

#### **General Hospital Devices Branch (GHDB)**

- Clinical electronic thermometers
- Hypodermic needles
- Intravascular catheters

#### **Respiratory Devices Branch (RPDB)**

- Ventilators
- Nebulizers
- Tracheobronchial catheters
- Portable oxygen units
- Oxygen generators

#### **Infection Control Devices Branch (INCB)**

- Patient examination gloves
- Sterilization wrap
- Sterilization process indicator
- Surgeon's gloves

#### **Dental Devices Branch (DEDB)**

- Endosseous dental implant
- Endosseous dental implant abutment
- Bone grafting material
- Intra-oral devices for snoring
- Dental cement
- Tooth shade resin material

## **Division of Cardiovascular Devices (DCD)**

### **Cardiac Diagnostics Devices Branch (CDDB)**

- Blood pressure monitors
- Implantable hemodynamic electrophysiology monitors
- Arrhythmia detectors
- Electrocardiogram
- Multiparameter monitors
- Diagnostic computers
- External defibrillation
- Diagnostic catheters

### **Cardiac Electrophysiology Devices Branch (CEDB)**

- Ablation catheters
- Ablation surgical instruments
- Mapping catheters
- Mapping systems

### **Circulatory Support Devices Branch (CSDB)**

- Ventricular assist devices
- Total artificial hearts
- Cardiopulmonary bypass
- Autotransfusion
- Compressible limb sleeves
- Thermal reg. system
- Hypothermia
- Injectable polymers for heart failure
- Cardiopulmonary resuscitation devices

### **Interventional Cardiology Devices Branch (ICDB)**

- Coronary stents
- PTCA catheters
- Coronary guidewires, introducers, guide/support/infusion catheter
- Coronary atherectomy, embolectomy
- Aortic coarctation stents

### **Implantable Electrophysiology Devices Branch (IEDB)**

- Pacemakers
- Defibrillators
- Cardiac resynchronization therapy
- Nerve stimulators
- Leads

### **Peripheral Interventional Devices Branch (PIDB)**

- Stents
- Atherectomy catheters
- Embolic protection
- Angioplasty catheters
- Embolectomy catheters
- Guidewires, introducers, guide/support/infusion catheter

### **Structural Heart Devices Branch (SHDB)**

- Replacement heart valves
- Heart valve repair devices
- Cardiac occluders
- Balloon valvuloplasty
- Adhesion barriers
- Pericardial patches
- Vessel guard
- Vascular hemostasis devices

### **Vascular Surgery Devices Branch (VSDB)**

- Endovascular grafts
- Vascular surgical sealants
- Vascular surgical grafts
- IVC filters
- Vascular embolization
- Vascular clamps

## **Division of Ophthalmic and Ear, Nose and Throat Devices (DOED)**

### **Contact Lenses and Retinal Devices (CLRD)**

- Contact lens
- Rigid gas permeable for extended wear
- Accessory to contact-cleaning and wetting agents
- Accessories to contact lens solution
- Rigid gas permeable contact lens care products
- Lens case
- Artificial eye cleaners
- Lubricants
- Orthokeratology lens system
- In-office tinting contact lens
- Intraocular gas
- Intraocular fluid
- Ophthalmic eye shield
- Ophthalmic sponge

- Collagen corneal shield
- Retinal prosthesis

#### **Diagnostic and Surgical Devices Branch (DSDB)**

- Optical coherence tomography
- Ophthalmic/fundus camera
- Ophthalmoscope
- Slit lamp biomicroscope
- Perimeter
- Tonometer
- Visual acuity chart
- Visual evoked potential
- Nystagmography devices
- Excimer lasers for LASIK
- Femtosecond lasers
- Ophthalmic beta radiation source
- Sunglasses
- Prescription eyewear
- Transcorneal electrical stimulation

#### **Intraocular and Corneal Implants Branch (ICIB)**

- Ophthalmic tantalum clip
- Ophthalmic conformer
- Artificial eye
- Absorbable implant
- Eye sphere implant
- Extraocular orbital implant
- Keratoprosthesis
- Intraocular lens
- Scleral shell
- Aqueous shunt
- Intraocular fluid
- Intraocular lens guides
- Eyelid weights
- Punctum plug
- Scleral plug
- Corneal storage media
- Orbital implant wrap
- Balloon catheter for retinal reattachment
- Endocapsular ring
- Epikeratophakia lenticules
- Intraocular- refractive
- Refractive corneal implant
- Tissue adhesive for ophthalmic use
- Sclera graft

- Scleral expansion bands
- Lacrimal system repair devices
- Capsular tension ring injector
- Orbital tissue expander

#### **Ear, Nose, and Throat Branch (ENTB)**

- Cochlear implants
- Auditory brainstem implants
- Implantable middle ear hearing devices
- Implantable hearing aids
- Hearing aids
- Tinnitus maskers
- Hearing screeners and hearing tests
- Middle ear prostheses
- Intranasal splints, stents, and packing materials
- Sinus balloon catheters
- Tympanostomy tubes and delivery systems
- Nasal endoscopes and bronchoscopes
- Vocal fold augmentation devices
- ENT drills and surgical instruments
- ENT stereotaxic devices
- ENT nerve locators/monitors
- Drug coated sinus stents
- Nasal irrigation/suction
- ENT devices for snoring and sleep apnea

### **Division of Neurological and Physical Medicine Devices (DNPMD)**

#### **Neurostimulation Devices Branch (NSDB)**

- Deep brain stimulation systems
- Spinal cord stimulation systems
- Implanted peripheral nerve stimulation systems
- Vagus nerve stimulation systems
- Other implanted stimulation systems for movement disorders or stroke
- Permanently implanted electrodes

#### **Neurodiagnostic and Neurosurgical Devices Branch (NNDB)**

- Cerebral-spinal fluid shunts
- Stereotactic equipment
- Surgical devices and endoscopes for brain and spinal cord
- Cerebral-vascular devices
- Neurosurgical lasers
- Diagnostic electromyography and nerve conduction velocity devices

- Brain hypothermia devices
- Electroencephalographic devices, including detection software
- Dura matter substitutes and sealant
- Cranioplasty materials

### **Physical Medicine and Neurotherapeutic Devices Branch (PNDB)**

- Neuro-psychiatric devices (e.g., transcranial magnetic stimulation, cranial electrotherapy)
- Wheelchairs and powered scooters
- Transcutaneous electrical nerve stimulators
- Powered muscle stimulators
- Bone growth stimulators
- Cutaneous electrodes
- Therapeutic infrared heat lamps
- Therapeutic massagers
- Functional electrical (neuromuscular) stimulators
- Diathermy (shortwave and ultrasound)
- Shockwave generators for pain relief
- Hot/cold physical therapy devices (e.g., powered heating pads)
- Prosthetic limbs
- Orthotics
- Powered exercise and physical therapy devices (e.g., multi-function physical therapy tables)
- Powered patient transport devices
- Powered traction equipment

## **Division of Orthopedic Devices (DOD)**

### **Joint Fixation Devices Branch One (JFDB1)**

- Joint prostheses
  - Knees
  - Shoulder
  - Elbow
  - Ankle
  - Toe
- Orthopaedic patient match guides
- Fracture fixation 1
  - Suture anchors
  - Bone fixation fasteners (pins)
  - Intramedullary nails
  - External fixators
  - Bone fixation staple
  - Cerclage wires
  - Nail/blade/plate combination

## **Joint Fixation Devices Branch Two (JFDB2)**

- Joint prostheses
  - Hips
  - Wrist
  - Finger
- Arthroscopes
- Ortho manual surgical instruments
- Ortho powered surgical instruments
- Fracture fixation 2
  - Bone plates
  - Bone screws
  - Pediatric plates

## **Restorative and Repair Devices Branch (RRDB)**

- Bone cements
- Bone morphogenetic proteins
  - Spinal fusion
  - Fracture fixation
- Bone void fillers
- Hyaluronic acid injectables
- Ligaments
- Tendons
- Meniscal repair
- Cartilage repair

## **Anterior Spine Devices Branch (ASDB)**

- Anterior/anterolateral plates
- Vertebral body replacements
- Total disc replacements
- Disc nucleus replacements
- Intervertebral body fusion devices

## **Posterior Spine Devices Branch (PSDB)**

- Posterior/pedicle screws systems
- Facet screw systems
- Spinous process spacers/plates
- Laminoplasty plates

## **Division of Surgical Devices**

### **General Surgery Devices Branch One (GSDB1)**

- Surgical lasers
- Low level lasers

- Infrared (solid state sources)
- Surgical lamps/cameras
- Light based imagining
- Light based diagnostics

#### **General Surgery Devices Branch Two (GSDB2)**

- Manual surgical instr.(includes ortho)
- Powered surgical instr. (includes ortho)
- Scopes (all types, includes arthroscopes)
- Cryo devices
- Computer asst/robotics surgery devices
- Biopsy devices
- Hypo/hyperthermia devices (surgical cooling)
- Electrosurgical devices

#### **Plastics and Reconstructive Surgery Devices Branch One (PRSB1)**

- Sutures
- Hemostatic agents
- Breast implants
- Silicone contouring – implants
- Liposuction
- Surgical meshes
- Surgical sealants

#### **Plastics and Reconstructive Surgery Devices Branch Two (PRSB2)**

- Wound dressings
- Soft tissue fillers
- Surgical sealants
- Dermal replacements
- Wound healing – stimulators
- Skin adhesives

### **Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)**

#### **Obstetrics/Gynecology Devices Branch (OGDB)**

- Assisted reproduction devices
- Urogynecologic surgical mesh
- Contraceptive devices
- Laparoscopic and hysteroscopic instrumentation
- Adhesion barrier products
- Endometrial ablation systems
- Fibroid treatment technologies
- Optical diagnostic spectroscopy



- Vaginal lubricants
- Catamenial products
- Electronic maternal/fetal monitors
- Breast pumps
- Fetal evaluation/surgery
- Pessaries/dilators/perineometers
- Cervical evaluation devices
- Ovarian cancer treatment

#### **Urology and Lithotripsy Devices Branch (ULDB)**

- Urethral bulking agents for urinary incontinence
- Drug-coated catheters and stents
- Implanted urethral stents
- Implanted prosthesis
- Prostate cancer and benign prostatic hyperplasia (BPH) treatments
- Lithotripters
- Endoscopes, GI and urology

#### **Renal Devices Branch (RNDB)**

- Dialysis
- Extracorporeal blood treatment
- Transplant solutions and systems
- Body composition analyzers
- Catheter lock solutions
- Ex vivo tissue culture media

#### **Gastroenterology Devices Branch (GEDB)**

- Obesity
- Gastroesophageal reflux disease stents
- Ingestible video cameras
- Feeding tubes