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 (DNPMED)**

**Neurostimulation Devices Branch (NSDB)**

- Deep brain stimulation systems
- Spinal cord stimulation systems
- Implantable 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 (GEVB)**

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