Examples

Non-Significant Risk Devices and Significant Risk Devices

The following examples are provided to assist sponsors and Institutional Review Boards (IRBs) in determining the appropriate risk category (i.e., non-significant or significant) for medical devices. The list includes many commonly used medical devices. Inclusion of a device in the non-significant risk category should not be viewed as a conclusive determination, because the proposed use of a device in a study is the ultimate determinant of the potential risk to subjects. It is unlikely that a device included in the significant risk category could be deemed a non-significant risk device because of the inherent risks associated with most such devices.

NON-SIGNIFICANT RISK DEVICES

- Low-power lasers for treatment of pain
- Caries removal solution
- Daily wear contact lenses and associated lens care products not intended for use directly in the eye (e.g., cleaners; disinfecting, rinsing, and storage solutions)
- Contact lens solutions intended for use directly in the eye (e.g., lubricating/rewetting solutions) using active ingredients or preservation systems with a history of prior ophthalmic/contact lens use or generally recognized as safe for ophthalmic use
- Conventional gastroenterology and urology endoscopes and/or accessories
- Conventional general hospital catheters (long-term percutaneous, implanted, subcutaneous, and intravascular)
- Conventional implantable vascular access devices (ports)
- Conventional laparoscopes, culdoscopes, and hysteroscopes
- Dental filling materials, cushions, or pads made from traditional materials and designs
- Dental repair kits and realigners
- Digital mammography (Note: an IDE is required when safety and effectiveness data that will be submitted in support of a marketing application are collected.)
- Electroencephalography (e.g., new recording and analysis methods, enhanced diagnostic capabilities)
- Externally worn monitors for insulin reactions
- Functional electrical neuromuscular stimulators
- General biliary catheters
- General urological catheters (e.g., Foley and diagnostic catheters)
- Jaundice monitors for infants
- Magnetic resonance imaging (MRI) devices within FDA-specified parameters
Examples of Non-Significant Risk Devices and Significant Risk Devices  
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- Manual image-guided surgery
- Menstrual pads (cotton or rayon, only)
- Menstrual tampons (cotton or rayon, only)
- Non-implantable electrical incontinence devices
- Non-implantable male reproductive aids with no components that enter the vagina
- OB/GYN diagnostic ultrasound within FDA-approved parameters
- Transcutaneous electric nerve stimulation (TENS) devices for treatment of pain
- Wound dressings, excluding absorbable hemostatic devices and dressings (also excluding interactive wound and burn dressings)

SIGNIFICANT RISK DEVICES

General Medical Use

Catheters
- Urology – urologic with anti-infective coatings
- General hospital – except for conventional long-term percutaneous, implanted, subcutaneous, and intravascular
- Neurological – cerebrovascular, occlusion balloon
- Cardiology – transluminal coronary angioplasty, intra-aortic balloon with control system

Anesthesiology
- Breathing gas mixers
- Bronchial tubes
- Electroanesthesia apparatus
- Epidural and spinal catheters
- Epidural and spinal needles
- Esophageal obturators
- Gas machines for anesthesia or analgesia
- High-frequency jet ventilators greater than 150 BPM
- Rebreathing devices
- Respiratory ventilators
- Tracheal tubes

Cardiovascular
- Aortic and mitral valvuloplasty catheters
- Arterial embolization devices
- Cardiac assist devices: artificial heart (permanent implant and short-term use)
- Cardiomyoplasty devices, intra-aortic balloon pumps, ventricular assist devices
- Cardiac bypass devices: oxygenators, cardiopulmonary non-roller blood pumps, closed chest devices
Examples of Non-Significant Risk Devices and Significant Risk Devices
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- Cardiac pacemaker/pulse generators: antitachycardia, esophageal, external transcutaneous, implantable
- Cardiopulmonary resuscitation (CPR) devices
- Cardiovascular/intravascular filters
- Coronary artery retroperfusion systems
- Coronary occluders for ductus arteriosus, atrial and septal defects
- Coronary and peripheral arthrectomy devices
- Extracorporeal membrane oxygenators (ECMO)
- Implantable cardioverters/defibrillators
- Laser coronary and peripheral angioplasty devices
- Myoplasty laser catheters
- Organ storage/transport units
- Pacing leads
- Percutaneous conduction tissue ablation electrodes
- Peripheral, coronary, pulmonary, renal, vena caval, and peripheral stents
- Replacement heart valves
- Radiofrequency (RF) catheter ablation and mapping systems
- Ultrasonic angioplasty catheters
- Vascular and arterial graft prostheses
- Vascular hemostasis devices

Dental

- Absorbable materials to aid in the healing of periodontal defects and other maxillofacial applications
- Bone morphogenic proteins with and without bone, e.g., hyrdoxyapatite (HA)
- Dental lasers for hard tissue applications
- Endosseous implants and associated bone filling and augmentation materials used in conjunction with the implants
- Subperiosteal implants
- Temporomandibular joint (TMJ) prostheses

Ear, Nose, and Throat

- Auditory brainstem implants
- Cochlear implants
- Laryngeal implants
- Total ossicular prosthesis replacements

Gastroenterology and Urology

- Anastomosis devices
- Balloon dilation catheters for benign prostatic hyperplasia (BPH)
Examples of Non-Significant Risk Devices and Significant Risk Devices

Biliary stents
Components of water treatment systems for hemodialysis
Dialysis delivery systems
Electrical stimulation devices for sperm collection
Embolization devices for general urological use
Extracorporeal circulation systems
Extracorporeal hyperthermia systems
Extracorporeal photopheresis systems
Femoral, jugular, and subclavian catheters
Hemodialyzers
Hemofilters
Implantable electrical urinary incontinence systems
Implantable penile protheses
Injectable bulking agents for incontinence
Lithotripters (e.g., electrohydraulic extracorporeal shock wave, laser, powered mechanical, ultrasonic)
Mechanical hydraulic urinary incontinence devices
Penetrating external penile rigidity devices with components that enter the vagina
Peritoneal dialysis devices
Peritoneal shunt
Plasmapheresis systems
Prostatic hyperthermia devices
Urethral occlusion devices
Urethral sphincter prostheses
Urological stents (e.g., ureteral, prostate)

**General and Plastic Surgery**

- Absorbable adhesion barrier devices
- Absorbable hemostatic agents
- Artificial skin and interactive wound and burn dressings
- Injectable collagen
- Implantable craniofacial prostheses
- Repeat access devices for surgical procedure
- Sutures
- Collagen implant material for use in ear, nose, and throat; orthopedics; plastic surgery; and urological and dental applications
- Surgical lasers for use in various medical specialties
- Tissue adhesives for use in neurosurgery, gastroenterology, ophthalmology, general and plastic surgery, and cardiology
General Hospital
- Implantable vascular access devices (ports) – if new routes of administration or new design
- Infusion pumps (implantable and closed-loop – depending on the infused drug)

Neurological
- Electroconvulsive therapy (ECT) devices
- Hydrocephalus shunts
- Implanted intracerebral/subcortical stimulators
- Implanted intracranial pressure monitors
- Implanted spinal cord and nerve stimulators and electrodes

Obstetrics and Gynecology
- Antepartum home monitors for non-stress tests
- Antepartum home uterine activity monitors
- Catheters for chorionic villus sampling (CVS)
- Catheters introduced into the fallopian tubes
- Cervical dilation devices
- Contraceptive devices
  - Cervical caps
  - Condoms (for men) made from new materials (e.g., polyurethane)
  - Contraceptive in vitro diagnostics (IVDs)
  - Diaphragms
  - Female condoms
  - Intrauterine devices (IUDs)
  - New electrosurgical instruments for tubal coagulation
  - New devices for occlusion of the vas deferens
  - Sponges
  - Tubal occlusion devices (bands or clips)
- Devices to prevent postoperative pelvic adhesions
- Embryoscopes and devices intended for fetal surgery
- Falloposcopes and falloposcopic delivery systems
- Intrapartum fetal monitors using new physiological markers
- New devices to facilitate assisted vaginal delivery
- Thermal systems for endometrial ablation

Ophthalmics
- Class III ophthalmic lasers
- Contact lens solutions intended for direct instillation (e.g., lubrication/rewetting solutions) in the eye using new active agents or preservatives with no history of prior ophthalmic/contact lens use or not generally recognized as safe for ophthalmic use
• Corneal implants
• Corneal storage media
• Epikeratophakia lenticules
• Extended-wear contact lens
• Eye valve implants (glaucoma implant)
• Intraocular lenses (IOLs) [21 CFR Part 813]
• Keratoprosthesis
• Retinal reattachment systems: fluids, gases, perfluorocarbons, perfluoropropane, silicone oil, sulfur hexafluoride, tacks
• Viscosurgical fluids

Orthopedics and Restorative
• Bone growth stimulators
• Calcium tri-phosphate hydroxyapatite ceramics
• Collagen and bone morphogenic protein meniscus replacements
• Implantable prostheses (ligament, tendon, hip, knee, finger)
• Computer-guided robotic surgery

Radiology
• Boron neutron capture therapy
• Hyperthermia systems and applicators