Creighton UNIVERSITY

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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

- 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

- 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
- Tempormandubular 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)

- 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 prostheses
- 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

- Electricoconvulsive 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]
- Keratoprostheses
- Retinal reattachment systems: fluids, gases, perfluorocarbons, perfluorpropane, silicone oil, suflur 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