

Examples of Nonsignificant and Significant Risk Devices

A. Nonsignificant Risk Devices

- Caries Removal Solution
- 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
- 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)
- Dental Filling Materials, Cushions or pads made from traditional materials and designs
- Denture Repair Kits and Realigners
- Digital Mammography
- Electroencephalography (e.g., new recording and analysis methods, enhanced diagnostic and capabilities, measuring depth of anesthesia if anesthetic administration is no based on device output)
- Externally Worn Monitors for Insulin Reactions
- Functional Non-Invasive Electrical Neuromuscular Stimulators
- General Biliary Catheters
- General Urological Catheters (e.g., Foley and Diagnostic catheters) for short term use (< 28 days)
- Jaundice Monitors for Infants
- Low Power Lasers for treatment of pain
- Magnetic Resonance Imaging (MRI) Devices within FDA specified parameters
- Manual Image Guided Surgery
- Menstrual Pads (Cotton or Rayon, only)
- Nonimplantable Electrical Incontinence Devices
- Nonimplantable Make Reproductive Aids with no components that enter the vagina
- Ob/Gyn Diagnostic Ultrasound within FDA approved parameters
- Partial Ossicular Replacement Prosthesis (PORP)
- Total Ossicular Replacement Prosthesis (TORP)
- Transcutaneous Electric Nerve Stimulations (TENS) Devices for treatment of pain (except for chest pain/angina)
- Ureteral Stents
- Urethral Occlusion Device for less than 14 days
- Wound Dressings, excluding absorbable Hemostatic devices and dressings (also excluding Interactive Wound and Burn Dressings that aid or are intended to aid in the healing process)

## B. Significant Risk Devices

### 1. General Medical Use

- Catheters for General Hospital use – except for conventional lone-term percutaneous, implanted, subcutaneous and intravascular
- Collagen Implant Material for use in ear, nose and throat, orthopedics, plastic surgery, 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

### 2. 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 Ventilators greater than 150 BPM
- Rebreathing Devices
- Tracheal tubes

### 3. Cardiovascular

- Annuloplasty Rings
- Aortic and Mitral Valvuloplasty Catheters
- Arterial Embolization Devices
- Atherectomy and Thrombectomy Catheters
- Cardiac Assist Devices: artificial hearts, ventricular assist devices, intra-aortic balloon pumps, cardiomyoplasty devices
- Cardiac Bypass Devices: oxygenators, cardiopulmonary blood pumps, axial flow pumps, closed chest devices (except Class I cardiovascular surgical instruments), heat exchangers, catheters/cannulae, tubing, arterial filter, reservoirs
- Cardiac mapping and Ablation Catheters
- Cardiac Pacemaker/Pulse Generators: antitachycardia, esophageal, external transcutaneous, implantable
- Cardiopulmonary Resuscitation (CPR) Devices
- Cardiovascular Intravascular (vena cava) Filters
- Coronary Artery Retroperfusion Systems
- Distal Embolic Protection Devices
- Extracorporeal Counterpulsation Devices
- Extracorporeal Membrane Oxygenators (ECMO)
- Implantable Cardioverters/Defibrillators

- Intravascular Brachytherapy Devices
  - Intravascular Stents
  - Laser Angioplasty Catheters
  - Organ Storage/Transport Units
  - Pacing Leads
  - Percutaneous Conduction Tissue Ablation Electrodes
  - Percutaneous Transluminal Angioplasty Catheters
  - Replacement Heart Valves
  - Transcatheter Cardiac Occluders for atrial and ventricular septal defects, patent foramen ovale and patent ductus arteriosus
  - Transmyocardial Revascularization, Percutaneous Myocardial Revascularization Devices
  - Ultrasonic Angioplasty Catheters
  - Vascular and Arterial Graft Prostheses
  - Vascular Hemostasis Devices
4. Dental
- Absorbable Materials to aid in the healing of periodontal defects and other maxillofacial applications
  - Bone Morphogenic Proteins with and without bone, e.g., Hydroxyapatite (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
5. Ear, Nose and Throat
- Absorbable Gelatin Sponge
  - Auditory Brainstem Implants
  - Endolymphatic Shunt Tubes with or without valve
  - ENT Cements/Adhesives
  - Implantable Bone Conduction Hearing Aids
  - Implantable Middle Ear Hearing Device
  - Injectable Teflon Paste
  - Laryngeal Implants
  - Synthetic Polymer Materials
  - Tissue Autofluorescent Devices
  - Vocal Cord Medialization (Augmentation) Devices
6. 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 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 or Thermal Ablation Devices
  - Retention Type (Foley) Balloon Catheters for long term use (greater than or equal to 28 days)
  - Suprapubic Urological Catheters and accessories
  - Urethral Occlusion Devices for greater than 14 days use
  - Urethral Sphincter Protheses
  - Urological Catheters with anti-microbial coatings
  - Urological Stents (e.g., urethral, prostate, etc.)
7. General and Plastic Surgery
- Absorbable Adhesion Barrier Devices
  - Absorbable Hemostatic Agents
  - Artificial Skin and Interactive Wound and Burn Dressings
  - Breast Implants
  - Injectable Collagen
  - Implantable Craniofacial Protheses
  - Repeat Access Devices for surgical procedures
  - Sutures
8. 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)

#### 9. Neurological

- Electroconvulsive Therapy (ECT) Devices
- Hydrocephalus Shunts
- Implanted Intracerebral/Subcortical Stimulators
- Implanted Intracranial Pressure Monitors
- Implanted Spinal Cord and Nerve Stimulators and Electrodes
- Neurological Catheters (e.g., cerebrovascular, occlusion balloon, etc.)
- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of chest pain/angina

#### 10. Obstetrics and Gynecology

- Abdominal Decompression Chamber
- 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:
  1. Cervical Caps
  2. Condoms (for men) made from new materials (e.g., polyurethane)
  3. Contraceptive In Vitro Diagnostics (IVDS)
  4. Diaphragms
  5. Female Condoms
  6. Intrauterine Devices (IUDs)
  7. New Electrosurgical Instruments for Tubal Coagulation
  8. New Devices for Occlusion of the Vas Deferens
  9. Sponges
  10. Tubal Occlusion Devices (Bands or Clips)
- Cryomyolysis
- Devices to Prevent Post-op Pelvic Adhesions
- Embryoscopes and Devices intended for fetal surgery
- Endometrial Ablation Systems
- Falloposcopes and Falloposcopic Deliver Systems
- Fundal Pressure Belt (for vaginal assisted delivery)
- Gamete and Embryo Surgical Systems
- Intrapartum Fetal Monitors using new physiological markers
- New Devices to Facilitate Assisted Vaginal Delivery
- Operative Hysteroscopy and Laparoscopy
- Uterine Artery Embolization

#### 11. Ophthalmics

- Aniridia Intraocular Lenses (IOLs) or Rings (for iris reconstruction)

- Capsular Tension Rings
- 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 Storage Media
- Extended Wear Contact Lens (i.e., including a single overnight use)
- Glaucoma Treatment Devices (e.g., trabeculoplasty devices, devices that treat ciliary bodies, devices that raise or lower intraocular pressure, aqueous shunt/drainage devices, etc.)
- Implants for Refractive Purposes (e.g., intraocular lenses, corneal implants, scleral expansion bands, etc.)
- Intraocular Lenses (IOLs)
- Deratoprostheses
- Refractive Surgical Devices (e.g., lasers, electrical current devices, thermal and non-thermal deratoplasty devices, ablation devices, expansion rings, treatment of ciliary bodies, etc.)
- Retinal Disease Treatment Devices (e.g., electrical stimulation devices to treat macular degeneration, lasers to ablate epiretinal membranes and vitreous strands, etc.)
- Retinal Prosthesis (implant)
- Retinal Reattachment Devices (e.g., fluids, gases, perfluorocarbons, perfluoropropane, silicone oil, sulfur hexafluoride, balloon catheter for retinal reattachment)
- Viscosurgical Fluids (viscoelastics)

### 13. Radiology

- Boron Neutron Capture Therapy
- Hyperthermia Systems and Applicators