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|  | **ชื่อหน่วยงาน สำนักงานสาธารณสุขจังหวัดพิษณุโลก**  กระทรวงสาธารณสุข |
| ตัวอย่างเครื่องมือทางการแพทย์ที่จะศึกษาที่มีความเสี่ยงน้อยและความเสี่ยงมาก |

ตัวอย่างเครื่องมือทางการแพทย์ที่จะศึกษาที่มีความเสี่ยงน้อย

# Non-significant Risk Device Studies

Examples:

* Bio-stimulation Lasers for treatment of pain
* Caries Removal Solution
* Daily Wear Contact Lenses and Associated Cleaners and Solutions
* Dental Filling Materials, Cushions or Pads made from traditional materials and designs
* Denture Repair Kits and Re-aligners
* Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)
* Externally worn Monitor for Insulin Reactions
* Jaundice Monitor for Infants
* Magnetic Resonance Imaging (MRI) Devices within specified physical parameters
* Menstrual Pads
* Menstrual Tampons of “old” materials (used prior to May 28, 1976)
* Non-implantable Male Reproductive Aids
* Ob/Gyn Diagnostic Ultrasound (within specified parameters)
* Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain
* Wound Dressings, excluding absorbable hemostatic devices and dressings

# ตัวอย่างเครื่องมือทางการแพทย์ที่จะศึกษาที่มีความเสี่ยงมาก

# SIGNIFICANT RISK DEVICE STUDIES

Examples:

##### General Medical Use

**Catheters:**

* Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra-aortic ballloon with control system
* Gastroenterology and Urology – biliary and urologic
* General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
* Neurology – cerebrovascular, occlusion balloon
* Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
* Lasers for use in Ob/Gyn, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
* Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

##### Anesthesiology

* Respiratory Ventilators
* Electro-anesthesia Apparatus
* Gas Machines for Anesthesia or Analgesia
* High Frequency Jet Ventilators greater than 150 BPM

##### Cardiovascular

* Arterial Embolization Device
* Artificial Heart, permanent implant and short term use
* Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
* Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, antitachycardia, esophageal
* Cardiovascular/Intravascular Filters
* Coronary Artery Retroperfusion System
* DC-Defibrillators
* Implantable Cardioverters
* Laser Coronary Angioplasty Device
* Pacemaker Programmer
* Percutaneous Conduction Tissue Ablation Electrode
* Replacement Heart Valve
* Vascular and Arterial Graft Prostheses

Dental

* Endosseous Implant

**Ear, Nose and Throat**

* Cochlear Implant
* Total Ossicular Prosthesis Replacement
* Gastroenterology and Urology
* Anastomosis Device
* Endoscope and/or Accessories
* Extracorporeal Hyperthermia System
* Extrocorporeal Photophersis System
* Extracorporeal Shock-Wave Lithotriptor
* Kidney Perfusion System
* Mechanical/Hydraulic Impotence and Incontinence Devices
* Implantable Penile Prosthesis
* Peritoneal Shunt

##### General and Plastic Surgery

* Absorbable Hemostatic Agents
* Artificial Skin
* Injectable Silicone
* Implantable Prostheses: chin, nose, cheek, ear
* Sutures

##### General Hospital

* Infusion Pumps: Implantable and closed-loop, depending on infused drug
* Implantable Vascular Access Devices

##### Neurology

* Hydrocephalus Shunts
* Implanted Intracerebral/Subcortical Stimulator
* Implanted Intracranial Pressure Monitor
* Impalnted Spinal Cord and Nerve Stimulators and Electrodes

##### Obstetrics and Gynecology

* Cervical Dilator
* Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
* Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

##### Ophthalmics

* Extended Wear Contacts Lens
* Intraocular Lens (investigations subject to 21 CFR 813)
* Eye Valve Implant
* Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluoropropane

##### Orthopedics

* Implantable Prostheses: ligament, tendon, hip, knee, finger
* Bone Growth Stimulator
* Calcium Tri-Phosphate/Hydroxyapatite Ceramics
* Xenografts

##### Radiology

* Hyperthermia Systems and Applicators

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