**有顯著危險的醫療器材研究**

舉例如下：

一般醫療使用General Medical Use

導管Catheters

* 心臟病學的診斷、處理、經管腔的冠狀血管成形術、有控制系統的主動脈氣球Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra-aortic balloon with control system
* 腸胃科學和泌尿科學的導管Gastroenterology and Urology – biliary and urologic
* 長期經皮、植入的、皮下和血管內醫療 General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
* 神經學-腦血管、阻塞氣球 Neurology – cerebrovascular, occlusion balloon
* 耳、鼻、喉科、骨科和整形外科手術使用的植入材料Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
* 婦產學、心臟病學、胃腸科學、泌尿科學、胸腔學、眼科學和神經學使用的鐳射Lasers for use in Ob/Gyn, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
* 供神經學、腸胃病學、眼科學、一般和整形外科和心臟病學使用組織黏著劑Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

麻醉使用Anesthesiology

* 麻醉用呼吸通氣醫療器材 Respiratory Ventilators
* 用電的麻醉儀器 Electro-anesthesia Apparatus
* 用於麻醉或者止痛的氣體機Gas Machines for Anesthesia or Analgesia
* 大於150 BPM的高頻噴射通氣療器材 High Frequency Jet Ventilators greater than 150 BPM
* 心血管Cardiovascular
* 心血管動脈栓塞醫療器材Arterial Embolization Device
* 永久插入移植和短期使用的人造心臟Artificial Heart, permanent implant and short term use
* 心臟的繞道系統︰氧合器、心肺血流幫浦、心室輔助醫療器材Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
* 心臟節律器/脈波器︰可植入、經皮、食道的 、抗心搏過速Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, antitachycardia, esophageal
* 心血管/血管內過濾器 Cardiovascular/Intravascular Filters
* 冠狀動脈再灌注系統 Coronary Artery Retroperfusion System
* 直流電心率去顫器DC-Defibrillators
* 可植入心臟節律調整器Implantable Cardioverters
* 鐳射冠狀血管成形術醫療器材Laser Coronary Angioplasty Device
* 心律調節的控制器 Pacemaker Programmer
* 經皮上傳導組織部分切除術電極 Percutaneous Conduction Tissue Ablation Electrode
* 替換的心臟瓣膜 Replacement Heart Valve
* 血管和動脈移植片、補綴物 Vascular and Arterial Graft Prostheses

牙科Dental

* 骨內式植體Endosseous Implant

耳鼻喉Ear, Nose and Throat

* 人工電子耳植入術Cochlear Implant
* 聽小骨全置換補綴物取代替換Total Ossicular Prosthesis Replacement Ossicular
* 腸胃病學和泌尿學Gastroenterology and Urology
* 吻合術儀器Anastomosis Device
* 內視鏡和試劑 附加物件Endoscope and/or Accessories
* 體外的增溫系統 Extracorporeal Hyperthermia System
* 體外攝影系統Extrocorporeal Photophersis System
* 體外震波碎石機Extracorporeal Shock-Wave Lithotriptor
* 洗腎系統Kidney Perfusion System
* 機械/水力陽萎失禁醫療器材Mechanical/Hydraulic Impotence and Incontinence Devices
* 植入的陰莖的補綴物Implantable Penile Prosthesis Penile Prosthesis
* 腹膜的分流器Peritoneal Shunt

一般及整形外科General and Plastic Surgery

* 可吸收的止血用品Absorbable Hemostatic Agents
* 人工皮Artificial Skin
* 注入矽膠Injectable Silicone
* 可植入的補綴物下巴、鼻子、面頰、耳朵Implantable Prostheses: chin, nose, cheek, ear
* 手術縫線Sutures

綜合醫學General Hospital

* 注入幫浦︰植入型及封閉型，取決於輸注的藥 Infusion Pumps: Implantable and closed-loop, depending on infused drug
* 植入血管的醫療器材Implantable Vascular Access Devices

神經醫學Neurology

* 腦積水分流Hydrocephalus Shunts
* 植入腦內/皮層刺激器Implanted Intracerebral/Subcortical Stimulator
* 植入顱內壓顯示器Implanted Intracranial Pressure Monitor
* 植入的脊髓和神經的刺激器和電極Impalnted Spinal Cord and Nerve Stimulators and Electrodes

婦產科Obstetrics and Gynecology

* 子宮頸擴張器Cervical Dilator
* 絨毛取樣導管，第II 階段(懷孕期中) Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
* 避孕醫療器材︰結紮、子宮帽、子宮隔板、子宮內的避孕型醫療器材(IUD)、海綿Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

眼科Ophthalmics

* 長戴形隱形眼鏡Extended Wear Contacts Lens
* 眼內透鏡的研究(以聯邦法條21章 813節為規範) Intraocular Lens (investigations subject to 21 CFR 813) Intraocular
* 眼睛瓣膜植入Eye Valve Implant
* 視網膜的重附著系統︰硫六氟化物、矽酮油、平頭釘、玻璃體內氣體Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluoropropane

骨科Orthopedics

* 植入韌帶、腱、臀、膝、手指 Implantable Prostheses: ligament, tendon, hip, knee, finger
* 刺激骨頭成長器Bone Growth Stimulator
* 鈣三磷酸鹽/氫氧磷灰石石膏Calcium Tri-Phosphate/Hydroxyapatite Ceramics
* 異體的移植物Xenografts

放射診斷Radiology

* 感熱系統和塗敷物Hyperthermia Systems and Applicators