

TITLE/TOPIC OF GUIDANCE	CONTACT
Implantable Middle Ear Hearing Device (Final)	Eric C. Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2018
Tinnitus Masking Devices	Do
Laryngoplastic Phonosurgery Devices	Do
Ear Plug Devices	Do
CATEGORY—PREMARKET REVIEW FOR REPRODUCTIVE, ABDOMINAL AND RADIOLOGICAL DEVICES	
Devices for Assisted Reproduction Technologies (ART)	Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, ext. 115
Embolization Agents for Uterine Fibroid Embolization	Do
Condoms	Do
Menstrual Tampons	Do
Devices for Vacuum Assisted Delivery	Do
Device Systems for Endometrial Ablation	Do
Class II Special Controls Guidance Document: External Penile Rigidity Devices	Janine Morris, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, ext. 117
Guidance for the Treatment of Prostate Cancer	Do
Guidance for Urethral Stents	Do
Class II Special Controls Guidance for Home Uterine Activity Monitors (Revised)	Do
Ultrasound Coupling Gel	Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, ext. 130
Diagnostic Ultrasound	Do
Cleaning and Disinfection of Radiological Devices	Do
Sheaths and Covers for Ultrasound Transducers	Do
Bone Sonometers (Revised)	Do
Class II Special Controls Guidance Document: Sorbent Hemoperfusion Systems (Draft) Bone Sonometers (Revised)	Carolyn Neuland, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1220, ext. 131
Content of Premarket Notification Submissions for Conventional and High Permeability Hemodialyzers, Hemoconcentrators, Hemofilters and Hemodiafilters (Revised)	Do
Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems	Do
Automated Blood Cell Separators for Therapeutic Purposes (Draft)	Do
Blood Access Devices for Hemodialysis (Draft)	Do
CATEGORY—COMPLIANCE AND INSPECTIONS	
Impact Resistance Lenses: Questions and Answers	Walter Snesko, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597, ext. 120
Medical Device Quality Systems Manual for Small Entities (Update)	Joseph Puleo, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597, ext. 116