

TITLE/TOPIC OF GUIDANCE	CONTACT
Cardiovascular Intravascular Filters (Revised)	Elisa Harvey, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262
Arrhythmia Detectors	Elias Mallis, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517
Medical Device Labeling—Suggested Format and Content (Withdrawal)	Robert Gatling, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190, ext. 140
Class II Special Control Guidance Document: Extracorporeal Life Support Devices (Draft)	Dina J. Fleischer, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 176
CATEGORY—PREMARKET REVIEW FOR CLINICAL LABORATORY DEVICES	
Over-the-Counter (OTC) Drugs of Abuse	Arleen Pinkos, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1243
Glucose Test Systems	Pat Bernhardt, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1243
Automated Coagulation Devices	Valerie Dada, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1293
Analytical and Clinical Validation of Multiplex Tests for Heritable DNA Markers and/or Mutations	Elizabeth Mansfield and Michele Schoonmaker, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1293
Class II Special Controls Guidance Document: Specific Bacteriophage, Antibody Conjugates, and Antigens for Antibody Detection for <i>Bacillus anthracis</i> and <i>Yersinia pestis</i>	Roxanne Shively, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096
Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems (Final)	Sally Selepak, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096
Draft Guidance on In Vitro Diagnostic (IVD) Device Studies	Jean Toth-Allen, Center for Devices and Radiological Health (HFZ-312), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301-594-4723, ext. 141
CATEGORY—PREMARKET REVIEW FOR GENERAL, RESTORATIVE AND NEUROLOGICAL DEVICES	
Guidance for Thermal Ablation Device 510(k)s; Draft Guidance for Industry and FDA	Binita Ashar, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1307
Class II Exempt Special Controls Guidance for Various Orthopedic Fixation Devices; Final Guidance for Industry	Hollace Rhodes, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036
Class II Special Controls Guidance Document: Knee Joint Patellofemoral and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses	Peter Allen, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036
Class II Special Controls Guidance Document: Surgical Suture	Anthony Watson, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090
Class II Special Controls Guidance Document: Processed Human Dura Mater (Draft)	Charles Durfor, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090
Class II Special Controls Guidance Document: Vascular and Neurological Embolization Devices (Draft)	Stephen Rhodes, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090