

part 807 of this chapter subject to § 880.9.

[67 FR 69121, Nov. 15, 2002]

**§ 880.6992 Medical washer-disinfector.**

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors."

(1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

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**PART 882—NEUROLOGICAL DEVICES**

**Subpart A—General Provisions**

- Sec.
- 882.1 Scope.
- 882.3 Effective dates of requirement for pre-market approval.
- 882.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

**Subpart B—Neurological Diagnostic Devices**

- 882.1020 Rigidity analyzer.
- 882.1030 Ataxiagraph.
- 882.1200 Two-point discriminator.
- 882.1240 Echoencephalograph.
- 882.1275 Electroconductive media.
- 882.1310 Cortical electrode.
- 882.1320 Cutaneous electrode.
- 882.1330 Depth electrode.
- 882.1340 Nasopharyngeal electrode.
- 882.1350 Needle electrode.
- 882.1400 Electroencephalograph.

- 882.1410 Electroencephalograph electrode/lead tester.
- 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.
- 882.1430 Electroencephalograph test signal generator.
- 882.1460 Nystagmograph.
- 882.1480 Neurological endoscope.
- 882.1500 Esthesiometer.
- 882.1525 Tuning fork.
- 882.1540 Galvanic skin response measurement device.
- 882.1550 Nerve conduction velocity measurement device.
- 882.1560 Skin potential measurement device.
- 882.1570 Powered direct-contact temperature measurement device.
- 882.1610 Alpha monitor.
- 882.1620 Intracranial pressure monitoring device.
- 882.1700 Percussor.
- 882.1750 Pinwheel.
- 882.1790 Ocular plethysmograph.
- 882.1825 Rheoencephalograph.
- 882.1835 Physiological signal amplifier.
- 882.1845 Physiological signal conditioner.
- 882.1855 Electroencephalogram (EEG) telemetry system.
- 882.1870 Evoked response electrical stimulator.
- 882.1880 Evoked response mechanical stimulator.
- 882.1890 Evoked response photic stimulator.
- 882.1900 Evoked response auditory stimulator.
- 882.1925 Ultrasonic scanner calibration test block.
- 882.1950 Tremor transducer.

**Subparts C–D [Reserved]**

**Subpart E—Neurological Surgical Devices**

- 882.4030 Skull plate anvil.
- 882.4060 Ventricular cannula.
- 882.4100 Ventricular catheter.
- 882.4125 Neurosurgical chair.
- 882.4150 Scalp clip.
- 882.4175 Aneurysm clip applier.
- 882.4190 Clip forming/cutting instrument.
- 882.4200 Clip removal instrument.
- 882.4215 Clip rack.
- 882.4250 Cryogenic surgical device.
- 882.4275 Dowel cutting instrument.
- 882.4300 Manual cranial drills, burrs, trephines, and their accessories.
- 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.
- 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.
- 882.4325 Cranial drill handpiece (brace).
- 882.4360 Electric cranial drill motor.
- 882.4370 Pneumatic cranial drill motor.
- 882.4400 Radiofrequency lesion generator.
- 882.4440 Neurosurgical headrests.
- 882.4460 Neurosurgical head holder (skull clamp).