§ 880.6990  

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 880.6991  Medical washer.

(a) Identification. A medical washer is a device that is intended for general medical purposes to clean 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.

(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.

(67 FR 69121, Nov. 15, 2002)

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Sec.
882.1 Scope.
882.3 Effective dates of requirement for premarket 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 Ataxiograph.
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.