§ 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.” The device is 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.

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