§ 880.6600 Ultraviolet (UV) radiation chamber disinfection device.

(a) *Identification.* An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.

(b) *Classification*—Class II (special controls). The special controls for this device are:

(1) Performance testing must demonstrate the following:

(i) The chamber's ability to control the UV radiation dose during operation.

(ii) The chamber's disinfection performance through microbial challenge testing.

(iii) Evidence that the equipment intended to be processed is UV compatible.

(iv) Validation of the cleaning and disinfection procedures.

(v) The ability of the device to continue to perform to all specification after cleaning and disinfection.

(vi) Whether the device generates ozone (if so, 21 CFR 801.415, Maximum acceptable level of ozone, applies).

(2) Appropriate software verification, validation, and hazard analysis must be performed.

(3) Appropriate analysis and/or testing must validate electrical safety, mechanical safety, and electromagnetic compatibility of the device in its intended use environment.

(4) The labeling must include:

(i) UV hazard warning labels.

(ii) Explanation of all displays and/or labeling on user interface.

(iii) Explanation of device safety interlocks.

(iv) Explanation of all disinfection cycle signals, cautions and warnings.

(v) Device operating procedures.

(vi) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.

(vii) Procedures to follow in case of UV lamp malfunction or failure.

(viii) Procedures for disposing of mercury-containing UV lamps, if applicable.

(ix) Identification of specific equipment that is compatible with the UV radiation dose generated by the device and that can safely undergo UV radiation low-level disinfection in the chamber device.

(x) Description of the required preparation of equipment for disinfection in the UV radiation chamber device.

(xi) Identification of the specific microbes used in successful performance testing of the device.

(xii) Validated instructions for cleaning and disinfection of the device.

[80 FR 72588, Nov. 20, 2015]

§ 880.6710 Medical ultraviolet water purifier.

(a) *Identification.* A medical ultraviolet water purifier is a device intended for medical purposes that is used to destroy bacteria in water by exposure to ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

§ 880.6730 Body waste receptacle.

(a) *Identification.* A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.

(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. The device also is 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.

[66 FR 38806, July 25, 2001]

§ 880.6740 Vacuum-powered body fluid suction apparatus.

(a) *Identification.* A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum