Food and Drug Administration, HHS

§ 880.6310 Medical device data system.

(a) Identification. (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
   (i) The electronic transfer of medical device data;
   (ii) The electronic storage of medical device data;
   (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
   (iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

(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.

§ 880.6315 Remote Medication Management System.

(a) Identification. A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient’s prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient’s prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient’s command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

(b) Classification. Class II (special controls). The special control is: The FDA guidance document entitled “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System.” See §880.1(e) for availability of this guidance document.

§ 880.6320 AC-powered medical examination light.

(a) Identification. An AC-powered medical examination light is an AC-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

(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.

§ 880.6350 Battery-powered medical examination light.

(a) Identification. A battery-powered medical examination light is a battery-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

(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.
§ 880.6375  Patient lubricant.

(a) Identification. A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

(b) Classification. Class I (general controls).


§ 880.6430  Liquid medication dispenser.

(a) Identification. A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.

(b) Classification. Class I (general controls).


§ 880.6450  Skin pressure protectors.

(a) Identification. A skin pressure protector is a device intended for medical purposes that is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient’s developing decubitus ulcers (bedsores).

(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 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.

[66 FR 38806, July 25, 2001]

§ 880.6500  Medical ultraviolet air purifier.

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

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

§ 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).

§ 880.6740  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