

§ 880.6320

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.

[72 FR 59177, Oct. 19, 2007]

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38806, July 25, 2001]

§ 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. 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

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§ 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).

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 46952, Sept. 10, 2001]

§ 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). 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]