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.

§ 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]

§ 880.6710  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).

§ 880.6730  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