## Food and Drug Administration, HHS

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 regulations 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]

#### §880.6375 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 regulations 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 regulations 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]

### §880.6500 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).

### §880.6730 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 regulations 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]