§878.4630

§ 878.4630 Ultraviolet lamp for dermatologic disorders.

(a) Identification. An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(b) Classification. Class II.

§878.4635 Ultraviolet lamp for tanning.

- (a) *Identification*. An ultraviolet lamp for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See § 1040.20 of this chapter.
- (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 §878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§878.4660 Skin marker.

- (a) *Identification*. A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.
- (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 §878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§878.4680 Nonpowered, single patient, portable suction apparatus.

- (a) *Identification*. A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.
- (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 §878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§878.4700 Surgical microscope and accessories.

- (a) *Identification*. A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.
- (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 §878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 20011

§878.4730 Surgical skin degreaser or adhesive tape solvent.

- (a) *Identification*. A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.
- (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 §878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 20011

$\S 878.4750$ Implantable staple.

- (a) *Identification*. An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.
 - (b) Classification. Class II.

§878.4760 Removable skin staple.

- (a) *Identification*. A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.
- (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in