

§ 878.4730

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]

§ 878.4730 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, 2001]

§ 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.

§ 878.4755 Absorbable lung biopsy plug.

(a) *Identification.* A preformed (polymerized) absorbable lung biopsy plug is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.

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(3) In vivo evaluation must demonstrate performance characteristics of the device, including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

(4) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

(5) Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

(6) The device must be demonstrated to be biocompatible.

(7) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labeling must include identification of compatible introducer needles.

[79 FR 13219, Mar. 10, 2014]

EFFECTIVE DATE NOTE: At 79 FR 13219, Mar. 10, 2014, § 878.4755 was added, effective Apr. 9, 2014.

§ 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 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]

§ 878.4780 Powered suction pump.

(a) *Identification.* A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

(b) *Classification.* Class II.