that does not include an antimicrobial agent, 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 84 FR 71814, Dec. 30, 2019]

§ 878.4371 Irrigating wound retractor device.

(a) *Identification.* An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible and evaluated for particulate matter.

(2) Performance data must demonstrate the sterility and pyrogenicity of the patient-contacting components of the device.

(3) Performance data must support shelf life by demonstrating continued functionality and sterility of the device over the identified shelf life.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must:

(i) Characterize the tear resistance, tensile strength, and elongation properties of the barrier material;

(ii) Demonstrate that the liquid barrier material is resistant to penetration by blood, and is non-flammable;

(iii) Characterize the forces required to deploy the device;

(iv) Characterize the device's ranges of operation, including flow rates and maximum suction pressures;

(v) Demonstrate the ability of the device irrigation apparatus to maintain a user defined or preset flow rate to the surgical wound; and

(vi) Demonstrate the ability of the device to maintain user defined or preset removal rates of fluid from the surgical wound.

(5) The labeling must include or state the following information:

(i) Device size or incision length range;

(ii) Method of sterilization;

(iii) Flammability classification;

(iv) Non-pyrogenic;

(v) Shelf life; and

(vi) Maximum flow rate and suction pressure.

[83 FR 24, Jan. 2, 2018]

§ 878.4380 Drape adhesive.

(a) *Identification.* A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.

(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 38802, July 25, 2001]

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) *Identification.* An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(b) *Classification.* Class II.

§ 878.4410 Low energy ultrasound wound cleaner.

(a) *Identification.* A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' See § 878.1(e) for the availability of this guidance document.

[70 FR 67355, Nov. 7, 2005]

§ 878.4420 Electrosurgical device for over-the-counter aesthetic use.

(a) *Identification.* An electrosurgical device for over-the-counter aesthetic