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 use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

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

(1) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested: Over-heating, power accuracy radiofrequency, pulse cycle, waveform, pulse duration, and device characterization parameters.

(2) Label comprehension and self-selection performance evaluation must demonstrate that the intended over-the-counter users can understand the package labeling and correctly choose the device for the indicated aesthetic use.

(3) Usability performance evaluation must demonstrate that the over-the-counter user can correctly use the device, based solely on reading the directions for use, to treat the indicated aesthetic use.

(4) Clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use to achieve the intended aesthetic results.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Instructions for cleaning the device must be validated.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety, including the mechanical integrity, of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include:

(i) Warnings, precautions, and contraindications to ensure the safe use of the device for the over-the-counter users.