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(i) A statement describing the potential risk of developing scalp metastasis.

(ii) Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

(iii) A summary of the non-clinical and/or clinical testing pertinent to use of the device.

(iv) A summary of the device technical parameters, including temperature cooling range and duration of cooling.

(v) A summary of the device- and procedure-related adverse events pertinent to use of the device.

(vi) Information on how the device operates and the typical course of treatment.

(6) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse effects/complications.

(ii) Information on how the device operates and the typical course of treatment.

(iii) Information on the patient population for which there is clinical evidence of effectiveness.

(iv) The potential risks and benefits associated with use of the device.

(v) Postoperative care instructions.

[81 FR 7453, Feb. 12, 2016]

§ 878.4370 Surgical drape and drape accessories.

(a) Identification. A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon’s finger into the rectum during performance of a transurethral prostatectomy.

(b) Classification. Class II.

§ 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.


§ 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]

§ 878.4440 Eye pad.

(a) Identification. An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.

(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.