

Food and Drug Administration, HHS

§ 878.4360

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]

§ 878.4300 Implantable clip.

(a) *Identification.* An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification.* Class II.

§ 878.4320 Removable skin clip.

(a) *Identification.* A removable skin clip is a clip-like device intended to connect skin 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]

§ 878.4340 Contact cooling system for aesthetic use.

(a) *Identification.* A contact cooling system for aesthetic use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive aesthetic use.

(b) *Classification.* Class II (special controls). The special controls for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use." See § 878.1(e) for the availability of this guidance document.

[76 FR 6553, Feb. 7, 2011]

§ 878.4350 Cryosurgical unit and accessories.

(a) *Identification*—(1) *Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories.* A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.

(2) *Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories.* A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue dur-

ing surgical procedures, including urological applications, by applying extreme cold.

(3) *Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories.* A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.

(b) *Classification.* Class II.

§ 878.4360 Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.

(a) *Identification.* A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

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

(1) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

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

(4) The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

(5) Labeling must include the following: