(4) Demonstrate that device is biocompatible.

(5) Demonstrate that device is electrically safe and electromagnetically compatible in its intended use environment.

(6) Labeling—(i) Sunlamp products. (A) The warning statement below must appear on all sunlamp products and must be placed in a black box. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement:

Attention: This sunlamp product should not be used on persons under the age of 18 years.

(B) Manufacturers shall provide validated instructions on cleaning and disinfection of sunlamp products between uses in the user instructions.

(ii) Sunlamp products and UV lamps intended for use in sunlamp products. Manufacturers of sunlamp products and UV lamps intended for use in sunlamp products shall provide or cause to be provided in the user instructions, as well as all consumer-directed catalogs, specification sheets, descriptive brochures, and Web pages in which sunlamp products or UV lamps intended for use in sunlamp products are offered for sale, the following contraindication and warning statements:

(A) “Contraindication: This product is contraindicated for use on persons under the age of 18 years.”

(B) “Contraindication: This product must not be used if skin lesions or open wounds are present.”

(C) “Warning: This product should not be used on individuals who have had skin cancer or have a family history of skin cancer.”

(D) “Warning: Persons repeatedly exposed to UV radiation should be regularly evaluated for skin cancer.”

(c) Performance standard. Sunlamp products and UV lamps intended for use in sunlamp products are subject to the electronic product performance standard at §1040.20 of this chapter.

[79 FR 31213, June 2, 2014]

§ 878.4660 Skin marker.

(a) Identification. A skin marker is a pen-like device intended to be used to write on the patient’s skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.

(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.


§ 878.4670 Internal tissue marker.

(a) Identification. An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.

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

(1) The device must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.

(2) Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.

(3) Performance data must demonstrate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating sterility, package integrity, device functionality, and material stability over the requested shelf life.

(5) Labeling must include:

(i) A warning that the device must not be used on a non-sterile surface prior to use internally.

(ii) An expiration date/shelf life.