

(ii) A statement that the safety and effectiveness of the device's use for uses other than the indicated aesthetic use are not known.

(iii) A summary of the clinical information used to establish effectiveness for each indicated aesthetic usage and observed adverse events.

[81 FR 42244, June 29, 2016]

§ 878.4430 Microneedling device for aesthetic use.

(a) *Identification.* A microneedling device for aesthetic use is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

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

(1) The technical specifications and needle characteristics must be identified, including needle length, geometry, maximum penetration depth, and puncture rate.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Accuracy of needle penetration depth and puncture rate;

(ii) Safety features built into the device to protect against cross-contamination, including fluid ingress protection; and

(iii) Identification of the maximum safe needle penetration depth for the device for the labeled indications for use.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

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

(5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.

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

for all software components of the device.

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

(8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.

(9) Labeling must include the following:

(i) Information on how to operate the device and its components and the typical course of treatment;

(ii) A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;

(iii) Validated methods and instructions for reprocessing of any reusable components;

(iv) Disposal instructions; and

(v) A shelf life.

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

(i) Information on how the device operates and the typical course of treatment;

(ii) The probable risks and benefits associated with use of the device; and

(iii) Postoperative care instructions.

[83 FR 26577, June 8, 2018]

§ 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.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4450 Nonabsorbable gauze for internal use.

(a) *Identification.* Nonabsorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures