

**§ 878.4440**

**21 CFR Ch. I (4–1–25 Edition)**

(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 from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.

(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 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

**§ 878.4452 Nonabsorbable expandable hemostatic sponge for temporary internal use.**

(a) *Identification.* A nonabsorbable expandable hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, non-absorbable radiopaque compressed sponges and may include an applicator to facilitate delivery into a wound.

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

(1) Performance data must demonstrate the biocompatibility of patient-contacting components.

(2) Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.

(3) Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.

(4) Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:

(i) Material specifications.

(ii) Immunogenicity.

(iii) Viral inactivation for animal-derived materials.

(5) 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) Absorption capacity.
- (ii) Extent of swelling.
- (iii) Mechanical properties.
- (iv) Expansion force/pressure.
- (v) Radiopacity.
- (vi) Deployment/applicator functionality.

(6) In vivo performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: Controls bleeding, does not promote adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:

- (i) Deployment.
- (ii) Control of bleeding.
- (iii) Radiopacity.
- (iv) Retrieval.
- (v) Assessment of local and systemic effects.

(7) Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.

(8) Labeling must include:

- (i) Specific instructions for deployment by emergency responders and retrieval by surgeons.
- (ii) Warnings, cautions, and limitations needed for safe use of the device.
- (iii) Information on how the device operates and the typical course of treatment.
- (iv) A detailed summary of the in vivo and human factors testing pertinent to use of the device.
- (v) Appropriate imaging information to ensure complete retrieval of device.
- (vi) An expiration date/shelf life.

[79 FR 34224, June 16, 2014]

**§ 878.4454 Non-absorbable, hemostatic gauze for temporary internal use.**

(a) *Identification.* A non-absorbable, hemostatic gauze for temporary internal use is a prescription device intended to be placed temporarily for control of severely bleeding wounds such as surgical wounds and traumatic

injuries. The gauze is coated or impregnated with a hemostatic material which may enhance hemostasis by physical means. The device is intended to be removed once the patient is stabilized.

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

(1) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Specifically testing must:

- (i) Demonstrate that the device is able to achieve hemostasis;
- (ii) Demonstrate that the device can be radiographically detected; and
- (iii) Assess pertinent safety endpoints including vascular obstruction and adhesion formation.

(2) The device must be demonstrated to be biocompatible.

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

- (i) In vitro clot assessment;
- (ii) Particulate release testing;
- (iii) Physical characterization, including swelling percent and particulate size;
- (iv) Chemical characterization;
- (v) Radiopacity testing; and
- (vi) Mechanical integrity testing, including tensile strength and tear strength.

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

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

(6) Labeling must include the following:

- (i) Instructions for use, including an instruction to remove all visible device components by irrigation;
- (ii) The maximum amount of time the device may be left within the body;
- (iii) A shelf life;
- (iv) A contraindication for intravascular use of the device; and
- (v) A warning regarding the potential for adhesion formation.

[83 FR 6794, Feb. 15, 2018]