§ 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.


§ 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.