§ 878.4014 Nonresorbable gauze/sponge for external use.

(a) Identification. A nonresorbable gauze/sponge for external use is a sterile or non-sterile device intended for medical purposes, such as to be placed directly on a patient’s wound to absorb exudate. It consists of a strip, piece, or pad made from open woven, nonwoven mesh, cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in §878.9. [64 FR 53929, Oct. 5, 1999]

§ 878.4015 Wound dressing with poly (dialyl dimethyl ammonium chloride) (pDADMAC) additive.

(a) Identification. A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2d degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

(b) Classification. Class II (special controls). The special control is: the FDA guidance document entitled “Class II Special Controls Guidance Document: Wound Dressing With Poly (Dialyl Dimethyl Ammonium Chloride) (pDADMAC) Additive.” See §878.1(e) for availability of this guidance document. [74 FR 53167, Oct. 16, 2009]