approximation, including pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. It may be coated or uncoated, undyed or dyed, and with or without a standard needle attached.

(b) Classification. Class II (special controls). The special control for the device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See §878.1(e) for the availability of this guidance document.

[67 FR 77676, Dec. 19, 2002]

§ 878.4930 Suture retention device.

(a) Identification. A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.

(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.


§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(a) Identification. A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to support a patient during diagnostic examinations or surgical procedures.

(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.


§ 878.4960 Operating tables and accessories and operating chairs and accessories.

(a) Identification. Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.

(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 §878.9.


§ 878.5010 Nonabsorbable poly(propylene terephthalate) suture.

(a) Identification. Nonabsorbable poly(propylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurring aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(propylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See §878.1(e) for the availability of this guidance document.