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.

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) Identification. Nonabsorbable poly(ethylene terephthalate) surgical suture is a monofilament, 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(ethylene 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 approved 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.

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) Identification. Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.