needle, osteotome, pliers, rasp, re-...

(b) Classification. Class I (general con-
trols). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §878.9.

§ 878.4830 Absorbable surgical gut su-
ture.

(a) Identification. An absorbable sur-
gical gut suture, both plain and chro-
mic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.

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

§ 878.4840 Absorbable polydioxanone surgical suture.

(a) Identification. An absorbable polydioxanone surgical suture is an ab-
sorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly (p-dioxanone) and is intended for use in soft tissue approximation, including pediatric cardio-
vascular tissue where growth is expected to occur, and ophthalmic sur-
gery. 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 Con-
trols Guidance Document: Surgical Su-
tures; Guidance for Industry and FDA.” See §878.1(e) for the availability of this guidance document.

§ 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.