needle, osteotome, pliers, rasp, re- 
tainer, retractor, saw, scalpel blade, 
scalpel handle, one-piece scalp, snare, 
spatula, stapler, disposable or reusable 
stripper, stylet, suturing apparatus for 
the stomach and intestine, measuring 
tape, and calipers. A surgical instru-
ment that has specialized uses in a spe-
cific medical specialty is classified in 
separate regulations in parts 868 through 892.

(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 the limitations in § 878.9.

§ 878.4810 Laser surgical instrument 
for use in general and plastic sur-
gery and in dermatology.

(a) Identification. (1) A carbon dioxide 
laser for use in general surgery and in 
dermatology is a laser device intended 
to cut, destroy, or remove tissue by 
light energy emitted by carbon dioxide.

(2) An argon laser for use in derma-
tology is a laser device intended to de-
stroy or coagulate tissue by light en-
ergy emitted by argon.

(b) Classification. (1) Class II.

(2) Class I for special laser gas mix-
tures used as a lasing medium for this 
class of lasers. The devices subject to 
this paragraph (b)(2) are exempt from 
the premarket notification procedures in 
subpart E of part 807 of this chapter, 
subject to the limitations in § 878.9.

§ 878.4810 Laser surgical instrument 
for use in general and plastic sur-
gery and in dermatology.

(a) Identification. (1) A carbon dioxide 
laser for use in general surgery and in 
dermatology is a laser device intended 
to cut, destroy, or remove tissue by 
light energy emitted by carbon dioxide.

(2) An argon laser for use in derma-
tology is a laser device intended to de-
stroy or coagulate tissue by light en-
ergy emitted by argon.

(b) Classification. (1) Class II.

(2) Class I for special laser gas mix-
tures used as a lasing medium for this 
class of lasers. The devices subject to 
this paragraph (b)(2) are exempt from 
the premarket notification procedures in 
subpart E of part 807 of this chapter, 
subject to the limitations in § 878.9.

§ 878.4810 Laser surgical instrument 
for use in general and plastic sur-
gery and in dermatology.

(a) Identification. (1) A carbon dioxide 
laser for use in general surgery and in 
dermatology is a laser device intended 
to cut, destroy, or remove tissue by 
light energy emitted by carbon dioxide.

(2) An argon laser for use in derma-
tology is a laser device intended to de-
stroy or coagulate tissue by light en-
ergy emitted by argon.

(b) Classification. (1) Class II.

(2) Class I for special laser gas mix-
tures used as a lasing medium for this 
class of lasers. The devices subject to 
this paragraph (b)(2) are exempt from 
the premarket notification procedures in 
subpart E of part 807 of this chapter, 
subject to the limitations in § 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 con-
trols). 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 car-
diovascular tissue where growth is ex-
pected 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 con-
trols). 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.
§ 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 be used 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.


§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) Identification. Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent 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 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.


§ 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.

(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.


§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) Identification. Nonabsorbable polyamide surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation. The polyamide 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 multifilament or