$878.5030 Multifilament in form; 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.

$878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

(a) **Identification.** Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

(b) **Classification.** Class II (special controls). Consensus standards and labeling restrictions.

$878.5040 Suction lipoplasty system.

(a) **Identification.** A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

(b) **Classification.** Class II (special controls). Consensus standards and labeling restrictions.