Food and Drug Administration, HHS

§ 878.5350 Needle-type epilator.

(a) Identification. A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the

(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.

[66 FR 20735, Apr. 18, 2000, as amended at 68 FR 32985, June 3, 2003]

Subpart F—Therapeutic Devices

§ 878.5070 Air-handling apparatus for a surgical operating room.

(a) Identification. Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) Classification. Class II.

§ 878.5350 Needle-type epilator.

(a) Identification. A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the