§ 878.5050 Surgical smoke precipitator.

(a) *Identification.* A surgical smoke precipitator is a prescription device intended for clearance of the visual field by precipitation of surgical smoke and other aerosolized particulate matter created during laparoscopic surgery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Adverse tissue reaction must be mitigated through the following:

(i) Chemical characterization and toxicological risk assessment of the treated surgical smoke.

(ii) Demonstration that the elements of the device that may contact the patient are biocompatible.

(2) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Performance data must demonstrate the sterility of the patient contacting components of the device.

(5) Performance data must support the shelf life of the sterile components of the device by demonstrating continued functionality, sterility, and package integrity over the identified shelf life.

(6) Animal simulated-use testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Device must be demonstrated to be effectively inserted, positioned, and removed from the site of use.

(ii) Device must be demonstrated to precipitate surgical smoke particulates to clear the visual field for laparoscopic surgeries.

(iii) Device must be demonstrated to be non-damaging to the site of use and animal subject.

(7) Labeling must identify the following:

(i) Detailed instructions for use.

(ii) Electrical safety and electromagnetic compatibility information.

(iii) A shelf life.

[83 FR 4143, Jan. 30, 2018]

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 (special controls). The device, when it is an air handling bench apparatus, an air handling room apparatus, or an air handling enclosure apparatus, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 84 FR 71814, Dec. 30, 2019]

§ 878.5080 Air-handling apparatus accessory.

(a) *Identification.* An air-handling apparatus accessory is a supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.

(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.

[84 FR 14870, Apr. 12, 2019]

§ 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 hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in