

§ 868.5420

for any electroanesthesia apparatus that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an electroanesthesia apparatus that was in commercial distribution before May 28, 1976. Any other electroanesthesia apparatus shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 868.5420 Ether hook.

(a) *Identification.* An ether hook is a device that fits inside a patient's mouth and that is intended to deliver vaporized ether.

(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 § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38795, July 25, 2001]

§ 868.5430 Gas-scavenging apparatus.

(a) *Identification.* A gas-scavenging apparatus is a device intended to collect excess anesthetic, analgesic, or trace gases or vapors from a patient's breathing system, ventilator, or extracorporeal pump-oxygenator, and to conduct these gases out of the area by means of an exhaust system.

(b) *Classification.* Class II (performance standards).

§ 868.5440 Portable oxygen generator.

(a) *Identification.* A portable oxygen generator is a device that is intended to release oxygen for respiratory therapy by means of either a chemical reaction or physical means (e.g., a molecular sieve).

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(b) *Classification.* Class II (performance standards).

§ 868.5450 Respiratory gas humidifier.

(a) *Identification.* A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

§ 868.5454 High flow humidified oxygen delivery device.

(a) *Identification.* A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:

(i) Alarm testing must be performed;

(ii) Continuous use thermal stability testing must be performed;

(iii) Humidity output testing must be performed; and

(iv) Blender performance testing must evaluate fraction of inspired oxygen (FiO_2) blending accuracy.

(3) Performance data must validate cleaning instructions for any reusable components of the device.

(4) Electrical safety, thermal safety, mechanical safety, electromagnetic compatibility, and radiofrequency identification testing must be performed.

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

(6) Labeling must include:

(i) A description of available FiO_2 ranges for different flowrates and inlet gas pressures;

(ii) Instructions for applicable flowrates for all intended populations;