§ 868.5250 Breathing circuit circulator.
(a) Identification. A breathing circuit circulator is a turbine device that is attached to a closed breathing circuit and that is intended to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.
(b) Classification. Class II (performance standards).

§ 868.5260 Breathing circuit bacterial filter.
(a) Identification. A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit.
(b) Classification. Class II (performance standards).

§ 868.5270 Breathing system heater.
(a) Identification. A breathing system heater is a device that is intended to warm breathing gases before they enter a patient’s airway. The device may include a temperature controller.
(b) Classification. Class II (performance standards).

§ 868.5280 Breathing tube support.
(a) Identification. A breathing tube support is a device that is intended to support and anchor a patient’s breathing tube(s).
(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.

§ 868.5290 Carbon dioxide absorbent.
(a) Identification. A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.
(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.

§ 868.5310 Carbon dioxide absorber.
(a) Identification. A carbon dioxide absorber is a device that is intended for medical purposes and that is used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.
(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.

§ 868.5320 Reservoir bag.
(a) Identification. A reservoir bag is a device, usually made of conductive rubber, intended for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient’s ventilation.
(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.

§ 868.5330 Breathing gas mixer.
(a) Identification. A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.
(b) Classification. Class II (performance standards).

§ 868.5340 Nasal oxygen cannula.
(a) Identification. A nasal oxygen cannula is a two-pronged device used to
§ 868.5350 Nasal oxygen catheter.

(a) Identification. A nasal oxygen catheter is a device intended to be inserted through a patient’s nostril to administer oxygen.

(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.


§ 868.5365 Posture chair for cardiac or pulmonary treatment.

(a) Identification. A posture chair for cardiac or pulmonary treatment is a device intended to assist in the rehabilitation and mobilization of patients with chronic heart or lung disease.

(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.


§ 868.5375 Heat and moisture condenser (artificial nose).

(a) Identification. A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by 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 the limitations in §868.9.


§ 868.5400 Electroanesthesia apparatus.

(a) Identification. An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to a patient’s head.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 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.


§ 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.