§ 868.5820 Dental protector.

(a) Identification. A dental protector is a device intended to protect a patient’s teeth during manipulative procedures within a patient’s oral cavity.

(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.


§ 868.5830 Autotransfusion apparatus.

(a) Identification. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

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

§ 868.5860 Pressure tubing and accessories.

(a) Identification. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(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.


§ 868.5870 Nonrebreathing valve.

(a) Identification. A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

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

§ 868.5880 Anesthetic vaporizer.

(a) Identification. An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

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

§ 868.5895 Continuous ventilator.

(a) Identification. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

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

§ 868.5905 Noncontinuous ventilator (IPPB).

(a) Identification. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient’s lungs or to assist a patient’s breathing.

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

§ 868.5915 Manual emergency ventilator.

(a) Identification. A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient’s airway.

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

§ 868.5925 Powered emergency ventilator.

(a) Identification. A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient’s airway.

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

§ 868.5935 External negative pressure ventilator.

(a) Identification. An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient’s ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.