§ 868.5655 Portable liquid oxygen unit.

(a) Identification. A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is intended to supplement gases to be inhaled by a patient, is sometimes accompanied by tubing and an oxygen mask. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

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

§ 868.5665 Powered percussor.

(a) Identification. A powered percussor is a device that is intended to transmit vibration through a patient’s chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

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

§ 868.5675 Rebreathing device.

(a) Identification. A rebreathing device is a device that is intended to transmit vibration through a patient’s chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

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

§ 868.5695 Incentive spirometer.

(a) Identification. An incentive spirometer is a device that is intended to transmit vibration through a patient’s chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

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

§ 868.5715 Nonpowered oxygen tent.

(a) Identification. A nonpowered oxygen tent is a device that encloses a patient’s head and upper body to contain oxygen delivered to the patient for breathing. This generic type of device includes infant oxygen hoods.

(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 §888.9.


§ 868.5725 Bronchial tube.

(a) Identification. A bronchial tube is a device used to differentially intubate a patient’s bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

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

§ 868.5735 Tracheal/bronchial differential ventilation tube.

(a) Identification. A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.

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

§ 868.5745 Inflatable tracheal tube cuff.

(a) Identification. An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient’s trachea.

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

§ 868.5765 Cuff spreader.

(a) Identification. A cuff spreader is a device used to install tracheal tube