Food and Drug Administration, HHS

§ 868.5700

§ 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 enables a patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(b) Classification. Class I (general controls).

§ 868.5690 Incentive spirometer. (a) Identification. An incentive spirometer is a device that indicates a patient’s breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation.

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

§ 868.5700 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...