Food and Drug Administration, HHS

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

§ 868.5955 Intermittent mandatory ventilation attachment.

(a) Identification. An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

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

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) Identification. A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient’s lungs above atmospheric pressure at the end of exhalation.

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

§ 868.5975 Ventilator tubing.

(a) Identification. Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the 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.


§ 868.5995 Tee drain (water trap).

(a) Identification. A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(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.


§ 868.6225 Nose clip.

(a) Identification. A nose clip is a device intended to close a patient’s external nares (nostrils) during diagnostic or therapeutic procedures.

(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. The device is also 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.