§ 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 administer oxygen to a patient through both nostrils.

(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.


§ 868.5350 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.