§ 868.5560 Gas mask head strap.

(a) Identification. A gas mask head strap is a device used to hold an anesthetic gas mask in position on a patient’s face.

(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.


§ 868.5570 Nonrebreathing mask.

(a) Identification. A nonrebreathing mask is a device fitting over a patient’s face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled 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.


§ 868.5580 Oxygen mask.

(a) Identification. An oxygen mask is a device placed over a patient’s nose, mouth, or tracheostomy to administer oxygen or aerosols.

(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.


§ 868.5590 Scavenging mask.

(a) Identification. A scavenging mask is a device positioned over a patient’s nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(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.


§ 868.5600 Venturi mask.

(a) Identification. A venturi mask is a device containing an air–oxygen mixing mechanism that dilutes 100 percent oxygen to a predetermined concentration and delivers the mixed gases to 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.


§ 868.5610 Membrane lung for long-term pulmonary support.

(a) Identification. A membrane lung for long-term pulmonary support is a device used to provide to a patient extracorporeal blood oxygenation for longer than 24 hours.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §868.3.


§ 868.5620 Breathing mouthpiece.

(a) Identification. A breathing mouthpiece is a rigid device that is inserted into a patient’s mouth and that connects with diagnostic or therapeutic respiratory devices.

(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.


§ 868.5630 Nebulizer.

(a) Identification. A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Heated, ultrasonic, gas, venturi, and