

Food and Drug Administration, HHS

§ 868.3

868.5810 Airway connector.
868.5820 Dental protector.
868.5830 Autotransfusion apparatus.
868.5860 Pressure tubing and accessories.
868.5870 Nonrebreathing valve.
868.5880 Anesthetic vaporizer.
868.5895 Continuous ventilator.
868.5905 Noncontinuous ventilator (IPPB).
868.5915 Manual emergency ventilator.
868.5925 Powered emergency ventilator.
868.5935 External negative pressure ventilator.
868.5955 Intermittent mandatory ventilation attachment.
868.5965 Positive end expiratory pressure breathing attachment.
868.5975 Ventilator tubing.
868.5995 Tee drain (water trap).

Subpart G—Miscellaneous

868.6100 Anesthetic cabinet, table, or tray.
868.6175 Cardiopulmonary emergency cart.
868.6225 Nose clip.
868.6250 Portable air compressor.
868.6400 Calibration gas.
868.6700 Anesthesia stool.
868.6810 Tracheobronchial suction catheter.
868.6820 Patient position support.
868.6885 Medical gas yoke assembly.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360f, 371.

SOURCE: 47 FR 31142, July 16, 1982, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 868 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

[52 FR 17734, May 11, 1987, as amended at 67 FR 76681, Dec. 13, 2002; 78 FR 18233, Mar. 26, 2013]

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the