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§ 868.6820

subpart E of part 807 of this chapter subject to §868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2314, Jan. 14, 2000]

§868.6820 Patient position support.

- (a) Identification. A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.
- (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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 20011

§ 868.6885 Medical gas voke assembly.

- (a) Identification. A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate
- (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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

PART 870—CARDIOVASCULAR **DEVICES**

Subpart A—General Provisions

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870.1 Scope.

870.3 Effective dates of requirement for premarket approval.

870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Cardiovascular Diagnostic **Devices**

870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

870.1100 Blood pressure alarm.

870.1110 Blood pressure computer.

870.1120 Blood pressure cuff.

870.1130 Noninvasive blood pressure measurement system.

870.1140 Venous blood pressure manometer.

870 1200 Diagnostic intravascular catheter

870.1210 Continuous flush catheter.

870.1220 Electrode recording catheter or electrode recording probe.

870.1230 Fiberoptic oximeter catheter.

870.1240 Flow-directed catheter.

870.1250 Percutaneous catheter. 870.1270 Intracavitary phonocatheter system.

870.1280 Steerable catheter.

870.1290 Steerable catheter control system.

870.1300 Catheter cannula.

870.1310 Vessel dilator for percutaneous catheterization.

870.1330 Catheter guide wire.

870.1340 Catheter introducer.

870.1350 Catheter balloon repair kit.

870.1360 Trace microsphere

Catheter tip occluder. 870.1370

Catheter stylet. 870.1380

870.1390 Trocar.

870.1425 Programmable diagnostic computer.

870.1435 Single-function, preprogrammed diagnostic computer.

870.1450 Densitometer

870.1650 Angiographic injector and syringe.

870.1660 Indicator injector.

870.1670 Syringe actuator for an injector.

870.1750 External programmable pacemaker pulse generator.

870.1800 Withdrawal-infusion pump.

870.1875 Stethoscope.

870.1915 Thermodilution probe.

Subpart C—Cardiovascular Monitoring **Devices**

870.2050 Biopotential amplifier and signal conditioner.

870.2060 Transducer signal amplifier and signal conditioner.

870.2100 Cardiovascular blood flowmeter. 870.2120 Extravascular blood flow probe.

870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

870.2310 Apex cardiograph

(vibrocardiograph).

870.2320 Ballistocardiograph.

870.2330 Echocardiograph.

870.2340 Electrocardiograph.

870.2350 Electrocardiograph lead switching adaptor.

870.2360 Electrocardiograph electrode.

870.2370 Electrocardiograph surface electrode tester.

870.2390 Phonocardiograph.

870.2400 Vectorcardiograph.

870.2450 Medical cathode-ray tube display.

870.2600 Signal isolation system.

870.2620 Line isolation monitor.

870.2640 Portable leakage current alarm.

870.2675 Oscillometer.

870.2700 Oximeter.

870.2710 Ear oximeter.

Impedance phlebograph. 870.2750

870.2770 Impedance plethysmograph.