§ 870.4300 Cardiopulmonary bypass gas control unit.

(a) Identification. A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

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

§ 870.4310 Cardiopulmonary bypass coronary pressure gauge.

(a) Identification. A cardiopulmonary bypass coronary pressure gauge is a device used in cardiopulmonary bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

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

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

(a) Identification. A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

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

§ 870.4330 Cardiopulmonary bypass on-line blood gas monitor.

(a) Identification. A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

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

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

(a) Identification. A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

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

§ 870.4350 Cardiopulmonary bypass oxygenator.

(a) Identification. A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions.”

§ 870.4360 Nonroller-type cardiopulmonary bypass blood pump.

(a) Identification. A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

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

(c) Date PMA or notice of completion of PDP is required. No effective date has been established of the requirement for premarket approval. See §870.3.

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) Identification. A roller-type cardiopulmonary bypass blood pump is