Food and Drug Administration, HHS

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) Identification. Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) Classification. (1) Class I. The device is classified as class I if it does not involve an electrical connection to the patient. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §870.9.

(2) Class II (special controls). The device is classified as class II if it involves an electrical connection to the patient.

§ 870.3945 Prosthetic heart valve sizer.

(a) Identification. A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(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 §870.9.

§ 870.4075 Endomyocardial biopsy device.

(a) Identification. An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.

(b) Classification. Class II (performance standards).
§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) **Identification.** A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

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

§ 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.

(a) **Identification.** A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.

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

§ 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) **Identification.** A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

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

§ 870.4230 Cardiopulmonary bypass defoamer.

(a) **Identification.** A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.

(b) **Classification.** Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions.”

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) **Identification.** A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

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

§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) **Identification.** A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

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

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

(a) **Identification.** A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

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

§ 870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter.

(a) **Identification.** A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a