

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

**§ 870.4200 Cardiopulmonary bypass accessory equipment.**

(a) *Identification.* Cardiopulmonary bypass accessory equipment are devices that have no contact with blood and that are 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.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989]

**§ 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 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 § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

**§ 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 III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has