

§ 870.4360

(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.”

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 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 a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

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

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

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

§ 870.4380 Cardiopulmonary bypass pump speed control.

(a) *Identification.* A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

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

§ 870.4390 Cardiopulmonary bypass pump tubing.

(a) *Identification.* A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood

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to flow through the cardiopulmonary bypass circuit.

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

§ 870.4400 Cardiopulmonary bypass blood reservoir.

(a) *Identification.* A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.

(b) *Classification.* Class II (performance standards), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter.

§ 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) *Identification.* A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

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

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) *Identification.* A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

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

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) *Identification.* A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

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

§ 870.4450 Vascular clamp.

(a) *Identification.* A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

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