§ 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).

§ 870.4330 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).

§ 870.4340 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.”

§ 870.4350 Cardiopulmonary bypass pump speed control.

(a) Identification. A cardiopulmonary bypass pump speed control is a device used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

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

§ 870.4360 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.