§ 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 Cardiopulmonary Bypass Arterial Line Blood Filter 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 blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

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

§ 870.4280 Cardiopulmonary prebypass filter.

(a) Identification. A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.

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

§ 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.

(a) Identification. A cardiopulmonary bypass adaptor, stopcock, manifold, or fitting is a device used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

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