$870.3935 Prosthetic heart valve holder.

(a) Identification. A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

$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 §870.9.

$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).