Food and Drug Administration, HHS

§ 870.4875 Intraluminal artery stripper.
(a) Identification. An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)
(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 con-
(b) Classification. Class II (performance standards).

§ 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).

§ 870.4400 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 classed into the same class as the defoamer or filter.

§ 870.4475 Surgical vessel dilator.
(a) Identification. A surgical vessel dilator 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).

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.
(a) Identification. A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a con-
(b) Classification. Class II (performance standards).

§ 870.4875 Intraluminal artery strip-
per.
(a) Identification. An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)
(b) Classification. Class II (performance standards).

§ 870.4450 Cardiovascular surgical instruments.
(a) Identification. Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.
(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 the limitations in §870.9.