natural valves. This device includes
valves constructed of prosthetic mate-
rials, biologic valves (e.g., porcine
valves), or valves constructed of a com-
bination of prosthetic and biologic ma-
terials.

(b) Classification. Class III (premarket
approval).

(c) Date premarket approval application
(PMA) or notice of completion of a prod-
uct development protocol (PDP) is re-
quired. A PMA or a notice of comple-
tion of a PDP is required to be filed
with the Food and Drug Administra-
tion on or before December 9, 1987 for
any replacement heart valve that was
in commercial distribution before May
28, 1976, or that has on or before De-
cember 9, 1987 been found to be sub-
stantially equivalent to a replacement
heart valve that was in commercial
distribution before May 28, 1976. Any
other replacement heart valve shall
have an approved PMA or a declared
completed PDP in effect before being
placed in commercial distribution.

[45 FR 7907–7971, Feb. 5, 1980, as amended at
52 FR 18163, May 13, 1987; 52 FR 23137, June
17, 1987]

§ 870.3935 Prosthetic heart valve hold-
er.

(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 notifica-
tion procedures in subpart E of part 807
of this chapter.

[45 FR 7907-7971, Feb. 5, 1980, as amended at
52 FR 18163, May 13, 1987; 52 FR 23137, June
17, 1987]

§ 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 con-
trols). The device is exempt from the
premarket notification procedures in subpart E of part 807 of this chapter
subject to § 870.9.

[65 FR 19319, Apr. 11, 2000]

§ 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 cir-
cuit.

(b) Classification. Class II (perform-
ance standards).