to measure blood flow in a chamber or vessel.
(b) Classification. Class II (performance standards).

§ 870.2300 Cardiac monitor (including
    cardiotachometer and rate alarm).
(a) Identification. A cardiac monitor
    (including cardiotachometer and rate
    alarm) is a device used to measure the
    heart rate from an analog signal pro-
    duced by an electrocardiograph,
    vectorcardiograph, or blood pressure
    monitor. This device may sound an
    alarm when the heart rate falls outside
    preset upper and lower limits.
(b) Classification. Class II (performance
    standards).

§ 870.2310 Apex cardiograph
    (vibrocardiograph).
(a) Identification. An apex cardio-
    graph (vibrocardiograph) is a device
    used to amplify or condition the signal
    from an apex cardiographic transducer
    and to produce a visual display of the
    motion of the heart; this device also
    provides any excitation energy re-
    quired by the transducer.
(b) Classification. Class II (performance
    standards).

§ 870.2320 Ballistocardiograph.
(a) Identification. A ballistocardiograph
    is a device, including a supporting
    structure on which the patient is placed,
    that moves in response to blood ejection
    from the heart. The device often provides a
    visual display.
(b) Classification. Class II (performance
    standards).

§ 870.2330 Echocardiograph.
(a) Identification. An echocardiograph
    is a device that uses ultrasonic energy
    to create images of cardiovascular
    structures. It includes phased arrays
    and two-dimensional scanners.
(b) Classification. Class II (performance
    standards).

§ 870.2340 Electrocardiograph.
(a) Identification. An electrocardio-
    graph is a device used to process the
    electrical signal transmitted through
    two or more electrocardiograph elec-
    trodes and to produce a visual display
    of the electrical signal produced by the
    heart.
(b) Classification. Class II (performance
    standards).

§ 870.2350 Electrocardiograph lead
    switching adaptor.
(a) Identification. An electrocardiog-
    raph lead switching adaptor is a pas-
    sive switching device to which electro-
    cardiograph limb and chest leads may
    be attached. This device is used to con-
    nect various combinations of limb and
    chest leads to the output terminals in
    order to create standard lead combina-
    tions such as leads I, II, and III.
(b) Classification. Class II (performance
    standards).

§ 870.2360 Electrocardiograph elec-
    trode.
(a) Identification. An electrocardio-
    graph electrode is the electrical con-
    ductor which is applied to the surface
    of the body to transmit the electrical
    signal at the body surface to a proc-
    essor that produces an electrocardio-
    gram or vectorcardiogram.
(b) Classification. Class II (special
    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. The
    special control for this device is the
    FDA guidance document entitled
    "Class II Special Controls Guidance
    Document: Electrocardiograph Elec-
    trodes." See §870.1(e) for availability
    information of guidance documents.
[45 FR 7907-7971, Feb. 5, 1980, as amended at
76 FR 43585, July 21, 2011]

§ 870.2370 Electrocardiograph surface
    electrode tester.
(a) Identification. An electrocardio-
    graph surface electrode tester is a de-
    vice used to test the function and ap-
    plication of electrocardiograph elec-
    trodes.
(b) Classification. Class II (performance
    standards).

§ 870.2390 Phonocardiograph.
(a) Identification. A phonocardiograph
    is a device used to amplify or condition
    the signal from a heart sound trans-
    ducer. This device furnishes the exci-
    tation energy for the transducer and