§ 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

(a) Identification. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

(b) Classification. Class II (special controls). The guidance document entitled “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm” will serve as the special control. See §870.1 for the availability of this guidance document.

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Subpart B—Cardiovascular Diagnostic Devices

§ 870.1100 Blood pressure alarm.

(a) Identification. A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.

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

§ 870.1110 Blood pressure computer.

(a) Identification. A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

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

§ 870.1120 Blood pressure cuff.

(a) Identification. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject’s blood pressure.

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

§ 870.1130 Noninvasive blood pressure measurement system.

(a) Identification. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body.

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

§ 870.1140 Venous blood pressure manometer.

(a) Identification. A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

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

§ 870.1200 Diagnostic intravascular catheter.

(a) Identification. An intravascular diagnostic catheter is a device used to
Food and Drug Administration, HHS

§ 870.1210 Continuous flush catheter.
(a) Identification. A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.
(b) Classification. Class II (performance standards).

§ 870.1220 Electrode recording catheter or electrode recording probe.
(a) Identification. An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.
(b) Classification. Class II (performance standards).

§ 870.1230 Fiberoptic oximeter catheter.
(a) Identification. A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.
(b) Classification. Class II (performance standards).

§ 870.1240 Flow-directed catheter.
(a) Identification. A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.
(b) Classification. Class II (performance standards).

§ 870.1250 Percutaneous catheter.
(a) Identification. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.
(b) Classification. Class II (performance standards).

§ 870.1270 Intracavitary phonocatheter system.
(a) Identification. An intracavitary phonocatheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.
(b) Classification. Class II (performance standards).

§ 870.1280 Steerable catheter.
(a) Identification. A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.
(b) Classification. Class II (performance standards).

§ 870.1290 Steerable catheter control system.
(a) Identification. A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.
(b) Classification. Class II (performance standards).

§ 870.1300 Catheter cannula.
(a) Identification. A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semiflexible structure which can be connected to a tube or connector.
(b) Classification. Class II (performance standards).

§ 870.1310 Vessel dilator for percutaneous catheterization.
(a) Identification. A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.