

a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17735, May 11, 1987]

**§ 870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).**

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring

life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2314, Jan. 14, 2000]

### Subpart B—Cardiovascular Diagnostic Devices

#### § 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.

[68 FR 61344, Oct. 28, 2003]

#### § 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 record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

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