

§ 882.9

21 CFR Ch. I (4–1–01 Edition)

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 17739, May 11, 1987]

§ 882.9 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 sci-

entific 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 2319, Jan. 14, 2000]

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.

(a) *Identification.* A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient’s limb to determine the effectiveness of drugs or other treatments.

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

§ 882.1030 Ataxiagraph.

(a) *Identification*. An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification*. Class I (general controls).

§ 882.1200 Two-point discriminator.

(a) *Identification*. A two-point discriminator is a device with points used for testing a patient's touch discrimination.

(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 § 882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

§ 882.1240 Echoencephalograph.

(a) *Identification*. An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

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

§ 882.1275 Electroconductive media.

(a) *Identification*. Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

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

§ 882.1310 Cortical electrode.

(a) *Identification*. A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

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

§ 882.1320 Cutaneous electrode.

(a) *Identification*. A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

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

§ 882.1330 Depth electrode.

(a) *Identification*. A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

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

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification*. A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

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

§ 882.1350 Needle electrode.

(a) *Identification*. A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

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

§ 882.1400 Electroencephalograph.

(a) *Identification*. An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

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

§ 882.1410 Electroencephalograph electrode/lead tester.

(a) *Identification*. An electroencephalograph electrode/lead