

**§ 880.9 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 2318, Jan. 14, 2000]

**Subpart B [Reserved]**

**Subpart C—General Hospital and Personal Use Monitoring Devices**

**§ 880.2200 Liquid crystal forehead temperature strip.**

- (a) *Identification.* A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes. The device displays the color changes of heat sensitive liquid crystals corresponding to the variation in the surface temperature of the skin. The liquid crystals, which are cholesteric esters, are sealed in plastic.
- (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 § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 63 FR 59228, Nov. 3, 1998]

**§ 880.2400 Bed-patient monitor.**

- (a) *Identification.* A bed-patient monitor is a battery-powered device placed under a mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.
- (b) *Classification.* Class I (general controls). The device is exempt from the