§ 872.9 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 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—Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) Identification. A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(b) Classification. Class I (general controls). The device is exempt from the
§ 872.1720  Pulp tester.
   (a) Identification. A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.
   (b) Classification. Class II.

§ 872.1730  Electrode gel for pulp testers.
   (a) Identification. An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
   (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 the limitations in §872.9.

§ 872.1740  Caries detection device.
   (a) Identification. The caries detection device is a device intended to show the existence of decay in a patient’s tooth by use of electrical current.
   (b) Classification. Class II.

§ 872.1745  Laser fluorescence caries detection device.
   (a) Identification. A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.
   (b) Classification. Class II, subject to the following special controls:
   (1) Sale, distribution, and use of this device are restricted to prescription use in accordance with §801.109 of this chapter.
   (2) Premarket notifications must include clinical studies, or other relevant information, that demonstrates that the device aids in the detection of tooth decay by measuring increased laser induced fluorescence; and
   (3) The labeling must include detailed use instructions with precautions that urge users to:
          (i) Read and understand all directions before using the device,
          (ii) Store probe tips under proper conditions,
          (iii) Properly sterilize the emitter-detector handpiece before each use, and
          (iv) Properly maintain and handle the instrument in the specified manner and condition.

§ 872.1800  Extraoral source x-ray system.
   (a) Identification. An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.
   (b) Classification. Class II.

§ 872.1810  Intraoral source x-ray system.
   (a) Identification. An intraoral source x-ray system is an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.
   (b) Classification. Class II.

§ 872.1820  Dental x-ray exposure alignment device.
   (a) Identification. A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in
§ 872.1830 Cephalometer.

(a) Identification. A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental x-rays.

(b) Classification. Class II.

§ 872.1840 Dental x-ray position indicating device.

(a) Identification. A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.

(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 the limitations in § 872.9.

§ 872.1850 Lead-lined position indicator.

(a) Identification. A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental x-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the x-rays by absorbing divergent radiation, and to prevent leakage of radiation.

(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 the limitations in § 872.9.

§ 872.1870 Sulfide detection device.

(a) Identification. A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.

(b) Classification. Class II (special controls). Prescription use in accordance with § 801.109 of this chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

§ 872.1905 Dental x-ray film holder.

(a) Identification. A dental x-ray film holder is a device intended to position and to hold x-ray film inside the mouth.

(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 the limitations in § 872.9.

§ 872.2050 Dental sonography device.

(a) Identification. A dental sonography device for monitoring—(1) Identification. A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) Classification. Class I. The device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 872.9.
(b) Dental sonography device for interpretation and diagnosis—(1) Identification. A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) Classification. Class II (special controls). The special control for this device is FDA's guidance document entitled “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.” [68 FR 67367, Dec. 2, 2003]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 872.3050 Amalgam alloy.
(a) Identification. An amalgam alloy is a device that consists of a metallic substance intended to be mixed with mercury to form filling material for treatment of dental caries.
(b) Classification. Class II.

§ 872.3060 Gold-based alloys and precious metal alloys for clinical use.
(a) Identification. Gold-based alloys and precious metal alloys for clinical use are mixtures of metals, the major components of which are gold, silver, or palladium. They also may contain a small quantity of copper or platinum. The device is intended to fabricate dental appliances, such as crowns and bridges, for patients.
(b) Classification. Class II.

§ 872.3080 Mercury and alloy dispenser.
(a) Identification. A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in