

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 handpick before each use, and

(iv) Properly maintain and handle the instrument in the specified manner and condition.

[65 FR 18235, Apr. 7, 2000]

§ 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 subpart E of part 807 of this chapter subject to the limitations in §872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38797, July 25, 2001]

§ 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.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

§ 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