

§ 872.4600

dental instrument handle, surgical tissue scissors, mouth mirror, orthodontic band driver, orthodontic band pusher, orthodontic band setter, orthodontic bracket aligner, orthodontic pliers, orthodontic ligature tucking instrument, forceps, for articulation paper, forceps for dental dressing, dental matrix band, matrix retainer, dental retractor, dental retractor accessories, periodontic or endodontic irrigating syringe, and restorative or impression material syringe.

(b) *Classification*. Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989]

§ 872.4600 Intraoral ligature and wire lock.

(a) *Identification*. An intraoral ligature and wire lock is a metal device intended to constrict fractured bone segments in the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.

(b) *Classification*. Class II.

§ 872.4620 Fiber optic dental light.

(a) *Identification*. A fiber optic dental light is a device that is a light, usually AC-powered, that consists of glass or plastic fibers which have special optical properties. The device is usually attached to a dental handpiece and is intended to illuminate a patient's oral structures.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63008, Dec. 7, 1994]

§ 872.4630 Dental operating light.

(a) *Identification*. A dental operating light, including the surgical headlight, is an AC-powered device intended to illuminate oral structures and operating areas.

(b) *Classification*. Class I. The device is exempt from the premarket notification

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procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996]

§ 872.4730 Dental injecting needle.

(a) *Identification*. A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

§ 872.4760 Bone plate.

(a) *Identification*. A bone plate is a metal device intended to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

(b) *Classification*. Class II.

§ 872.4840 Rotary scaler.

(a) *Identification*. A rotary scaler is an abrasive device intended to be attached to a powered handpiece to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.

(b) *Classification*. Class II.

§ 872.4850 Ultrasonic scaler.

(a) *Identification*. An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

(b) *Classification*. Class II.

§ 872.4880 Intraosseous fixation screw or wire.

(a) *Identification*. An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.

(b) *Classification*. Class II.

§ 872.4920 Dental electro-surgical unit and accessories.

(a) *Identification*. A dental electro-surgical unit and accessories is