

with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs.

(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 38799, July 25, 2001]

§ 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.

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) *Identification*. A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

(b) *Classification*. Class II (special controls). The special controls for this device is FDA's guideline entitled "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline." See § 872.1(e) for the availability of this guidance document.

[78 FR 79310, Dec. 30, 2013]

§ 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 den-

tal 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 electrosurgical unit and accessories.

(a) *Identification*. A dental electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is intended to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

(b) *Classification*. Class II.

Subpart F—Therapeutic Devices

§ 872.5410 Orthodontic appliance and accessories.

(a) *Identification*. An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.

(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 63009, Dec. 7, 1994; 66 FR 38799, July 25, 2001]