

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

[52 FR 30097, Aug. 12, 1987; 52 FR 49250, Dec. 30, 1987]

**§ 872.6100 Anesthetic warmer.**

(a) *Identification.* An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.

(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 60 FR 38900, July 28, 1995]

**§ 872.6140 Articulation paper.**

(a) *Identification.* Articulation paper is a device composed of paper coated with an ink dye intended to be placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994]

**§ 872.6200 Base plate shellac.**

(a) *Identification.* Base plate shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

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

**§ 872.6250 Dental chair and accessories.**

(a) *Identification.* A dental chair and accessories is a device, usually AC-powered, in which a patient sits. The device is intended to properly position a patient to perform dental procedures. A dental operative unit may be attached.

(b) *Classification.* Class I. The dental chair without the operative unit 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 63009, Dec. 7, 1994]

**§ 872.6290 Prophylaxis cup.**

(a) *Identification.* A prophylaxis cup is a device made of rubber intended to be held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989]

**§ 872.6300 Rubber dam and accessories.**

(a) *Identification.* A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting the tooth through the hole in the center. The device includes the rubber dam, rubber dam

§ 872.6350

clamp, rubber dam frame, and forceps for a rubber dam clamp.

(b) *Classification.* Class I. The accessories to the device, i.e., rubber dam clamp, rubber dam frame and forceps for a rubber dam clamp, are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994]

§ 872.6350 Ultraviolet detector.

(a) *Identification.* An ultraviolet detector is a device intended to provide a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.

(b) *Classification.* Class II.

§ 872.6390 Dental floss.

(a) *Identification.* Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

(b) *Classification.* Class I. If the device is made of inert materials and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity, 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 61 FR 1121, Jan. 16, 1996]

§ 872.6475 Heat source for bleaching teeth.

(a) *Identification.* A heat source for bleaching teeth is an AC-powered device that consists of a light or an electric heater intended to apply heat to a tooth after it is treated with a bleaching agent.

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

21 CFR Ch. I (4-1-98 Edition)

procedures in subpart E of part 807 of this chapter.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994]

§ 872.6510 Oral irrigation unit.

(a) *Identification.* An oral irrigation unit is an AC-powered device intended to provide a pressurized stream of water to remove food particles from between the teeth and promote good periodontal (gum) condition.

(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 63009, Dec. 7, 1994]

§ 872.6570 Impression tube.

(a) *Identification.* An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989]

§ 872.6640 Dental operative unit and accessories.

(a) *Identification.* A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, and oral cavity evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.