

§ 872.6650

part 807 of this chapter subject to § 872.9.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 65 FR 2315, Jan. 14, 2000]

§ 872.6650 **Massaging pick or tip for oral hygiene.**

(a) *Identification.* A massaging pick or tip for oral hygiene is a rigid, pointed device intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition.

(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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation 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 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 872.6660 **Porcelain powder for clinical use.**

(a) *Identification.* Porcelain powder for clinical use is a device consisting of a mixture of kaolin, felspar, quartz, or other substances intended for use in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in prosthetic dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.

(b) *Classification.* Class II.

§ 872.6670 **Silicate protector.**

(a) *Identification.* A silicate protector is a device made of silicone intended to be applied with an absorbent tipped applicator to the surface of a new restoration to exclude temporarily fluids from its surface.

(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. If

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the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation 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 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 872.6710 **Boiling water sterilizer.**

(a) *Identification.* A boiling water sterilizer is an AC-powered device that consists of a container for boiling water. The device is intended to sterilize dental and surgical instruments by submersion in the boiling water in the container.

(b) *Classification.* Class I (general controls).

[55 FR 48439, Nov. 20, 1990, as amended at 66 FR 46952, Sept. 10, 2001]

§ 872.6730 **Endodontic dry heat sterilizer.**

(a) *Identification.* An endodontic dry heat sterilizer is a device intended to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.

(b) *Classification.* Class III.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before April 21, 1997, for any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, or that has on or before April 21, 1997, been found to be substantially equivalent to the endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976. Any other endodontic dry heat sterilizer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 62 FR 2902, Jan. 21, 1997; 62 FR 31512, June 10, 1997]