

Food and Drug Administration, HHS

§ 872.6140

such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece. The device includes the abrasive disk, guard for an abrasive disk, abrasive point, polishing agent strip, and polishing wheel.

(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 13830, Apr. 5, 1989; 66 FR 38799, July 25, 2001]

§ 872.6030 Oral cavity abrasive polishing agent.

(a) *Identification.* An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).

(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]

§ 872.6050 Saliva absorber.

(a) *Identification.* A saliva absorber is a device made of paper or cotton intended to absorb moisture from the oral cavity during dental procedures.

(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 13830, Apr. 5, 1989; 66 FR 38799, July 25, 2001]

§ 872.6070 Ultraviolet activator for polymerization.

(a) *Identification.* An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.

(b) *Classification.* Class II.

§ 872.6080 Airbrush.

(a) *Identification.* An airbrush is an AC-powered device intended for use in conjunction with articulation paper. The device uses air-driven particles to roughen the surfaces of dental restorations. Uneven areas of the restorations are then identified by use of articulation paper.

(b) *Classification.* Class II. The special control for this device is International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety."

[52 FR 30097, Aug. 12, 1987; 52 FR 49250, Dec. 30, 1987, as amended at 71 FR 17144, Mar. 31, 2006]

§ 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 (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 60 FR 38900, July 28, 1995; 66 FR 38799, July 25, 2001]

§ 872.6140 Articulation paper.

(a) *Identification.* Articulation paper is a device composed of paper coated