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.


§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.


§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.


§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.


§872.6140 Articulation paper.

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