§ 872.3140 Resin applicator.

(a) Identification. A resin applicator is a brushlike device intended for use in spreading dental resin on a tooth during application of tooth shade material.

(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, the device is exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 872.3150 Articulator.

(a) Identification. An articulator is a mechanical device intended to simulate movements of a patient’s upper and lower jaws. Plaster casts of the patient’s teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient’s jaws. An articulator is intended to fit dentures or provide orthodontic treatment.

(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, the device is exempt from the current good manufacturing practice requirements of the quality system regulation 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.