Food and Drug Administration, HHS

§ 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

§ 872.3110  Dental amalgam capsule.
(a) Identification. A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.

(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.


§ 872.3110  Dental amalgamator.
(a) Identification. A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental caries.

(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.


§ 872.3110  Dental amalgam capsule.
(a) Identification. A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.

(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.


§ 872.3140  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.


§ 872.3165 Precision attachment.

(a) Identification. A precision attachment or preformed bar is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use in prosthetic dentistry in conjunction with removable partial dentures. Various forms of the device are intended to connect a lower partial denture with another lower partial denture, to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a partial denture.

(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.


§ 872.3200 Resin tooth bonding agent.

(a) Identification. A resin tooth bonding agent is a device material, such as methylmethacrylate, intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.

(b) Classification. Class II.

§ 872.3220 Facebow.

(a) Identification. A facebow is a device intended for use in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is intended for use in placing denture casts accurately into an articulator (§§872.3150) and thereby aiding correct placement of artificial teeth into a denture base.

(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.


§ 872.3240 Dental bur.

(a) Identification. A dental bur is a rotary cutting device made from carbon steel or tungsten carbide intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.

(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.


§ 872.3250 Calcium hydroxide cavity liner.

(a) Identification. A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.

(b) Classification. Class II.