Food and Drug Administration, HHS

§ 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. 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.


§ 872.3150 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. 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.