silver alloy is intended to be mixed
with mercury to form dental amalgam.

(b) Classification. Class I (general con-
trols). 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 54
FR 133830, Apr. 5, 1989; 66 FR 38797, July 25,
2001]

§ 872.3130 Preformed anchor.

(a) Identification. A preformed anchor
is a device made of austenitic alloys or
alloys containing 75 percent or greater
gold or metals of the platinum group
intended to be incorporated into a den-
tal appliance, such as a denture, to
help stabilize the appliance in the pa-
tient’s mouth.

(b) Classification. Class I (general con-
trols). 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 63008, Dec. 7, 1994; 66 FR 38797, July 25,
2001]

§ 872.3140 Resin applicator.

(a) Identification. A resin applicator is
a brushlike device intended for use in
spreading dental resin on a tooth dur-
ing application of tooth shade mate-
rial.

(b) Classification. Class I (general con-
trols). 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 ex-
empt from the current good manufac-
turing practice requirements of the
quality system regulation in part 820 of
this chapter, with the exceptions of
§820.180, with respect to general re-
quirements concerning records, and
§820.198, with respect to complaint
files.

[52 FR 30097, Aug. 12, 1987, as amended at 54
FR 133830, Apr. 5, 1989; 66 FR 38797, July 25,
2001]

§ 872.3150 Articulator.

(a) Identification. An articulator is a
mechanical device intended to simu-
late movements of a patient’s upper
and lower jaws. Plaster casts of the pa-
tient’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 treat-
ment.

(b) Classification. Class I (general con-
trols). 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 ex-
empt from the current good manufac-
turing practice requirements of the
quality system regulation in part 820 of
this chapter, with the exceptions of
§820.180, with respect to general re-
quirements concerning records, and
§820.198, with respect to complaint
files.

[52 FR 30097, Aug. 12, 1987, as amended at 59
FR 63008, Dec. 7, 1994; 66 FR 38797, July 25,
2001]

§ 872.3200 Resin tooth bonding agent.

(a) Identification. A resin tooth bond-
ing 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.