§ 872.3260 Cavity varnish.

(a) Identification. Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

(b) Classification. Class II.

§ 872.3275 Dental cement.

(a) Zinc oxide-eugenol—Identification. Zinc oxide-eugenol is a device composed of zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

(2) 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 §872.9.

(b) Dental cement other than zinc oxide-eugenol—Identification. Dental cement other than zinc oxide-eugenol is a device composed of various materials other than zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

(2) Classification. Class II.


§ 872.3285 Preformed clasp.

(a) Identification. A preformed clasp or a preformed wire clasp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient's mouth by fastening the appliance to an adjacent tooth.

(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.


§ 872.3300 Hydrophilic resin coating for dentures.

(a) Identification. A hydrophilic resin coating for dentures is a device that consists of a water-retaining polymer that is intended to be applied to the base of a denture before the denture is inserted into the patient's mouth to improve denture retention and comfort.

(b) Classification. Class II.

§ 872.3310 Coating material for resin fillings.

(a) Identification. A coating material for resin fillings is a device intended to be applied to the surface of a restorative resin dental filling to attain a smooth, glaze-like finish on the surface of the filling.

(b) Classification. Class II.

§ 872.3330 Preformed crown.

(a) Identification. A preformed crown is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is intended for use as a functional restoration until a permanent crown is constructed. The device also may be intended for use as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.

(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.


§ 872.3350 Gold or stainless steel cusp.

(a) Identification. A gold or stainless steel cusp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and
metals of the platinum group or stain-
less steel intended to provide a perma-

nent cusp (a projection on the chewing
surface of a tooth) to achieve occlusal
harmony (a proper bite) between the
teeth and a removable denture.

(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.

§ 872.3360 Preformed cusp.

(a) Identification. A performed cusp is
a prefabricated device made of plastic
or austenitic alloys or alloys con-
taining 75 percent or greater gold and
metals of the platinum group intended
to be used as a temporary cusp (a pro-
jection on the chewing surface of a
tooth) to achieve occlusal harmony (a
proper bite) before permanent resto-

ration of a tooth.

(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.

§ 872.3360 Preformed cusp.

(a) Identification. A performed cusp is
a prefabricated device made of plastic
or austenitic alloys or alloys con-
taining 75 percent or greater gold and
metals of the platinum group intended
to be used as a temporary cusp (a pro-
jection on the chewing surface of a
tooth) to achieve occlusal harmony (a
proper bite) before permanent resto-

ration of a tooth.

(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.

§ 872.3400 Karaya and sodium borate
with or without acacia denture ad-
hesive.

(a) Identification. A karaya and so-
dium borate with or without acacia
denture adhesive is a device composed
of karaya and sodium borate with or
without acacia intended to be applied
to the base of a denture before the den-
ture is inserted into patient’s mouth to
improve denture retention and com-
fort.

(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.

§ 872.3410 Ethylene oxide homopolymer
and/or carboxymethylcellulose sodium
denture adhesive.

(a) Identification. An ethylene oxide
homopolymer and/or carboxymethylcellulose sodium den-
ture adhesive is a device containing
ethylene oxide homopolymer and/or
carboxymethylcellulose sodium in-
tended to be applied to the base of a
denture before the denture is inserted
in a patient’s mouth to improve den-
ture retention and comfort.

(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.

§ 872.3420 Carboxymethylcellulose so-
dium and cationic polyacrylamide
polymer denture adhesive.

(a) Identification. A carboxymethylcellulose sodium and
cationic polyacrylamide polymer den-
ture adhesive is a device composed of
carboxymethylcellulose sodium and
cationic polyacrylamide polymer in-
tended to be applied to the base of a
denture before the denture is inserted
in a patient’s mouth to improve den-
ture retention and comfort.

(b) Classification. Class III.