

§ 872.3410

21 CFR Ch. I (4-1-11 Edition)

completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976. Any other karaya and sodium borate with or without acacia denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50706, Sept. 27, 1996; 65 FR 2315, Jan. 14, 2000]

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

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

(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.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

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

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976. Any other carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996]

§ 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.

(a) *Identification.* Ethylene oxide homopolymer and/or karaya denture adhesive is a device composed of ethylene oxide homopolymer and/or karaya intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* (1) Class I if the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day's use. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 65 FR 2315, Jan. 14, 2000]

§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

(a) *Identification.* A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is

inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyacrylamide polymer (modified cationic) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996]

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

(a) *Identification.* A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(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.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

(a) *Identification.* Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and

carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996]

§ 872.3520 OTC denture cleanser.

(a) *Identification.* An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

(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.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]