§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium 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 § 872.9.

§ 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.

§ 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.