§ 872.5470

(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.


§ 872.5470 Orthodontic plastic bracket.

(a) Identification. An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

(b) Classification. Class I.

§ 872.5500 Extraoral orthodontic headgear.

(a) Identification. An extraoral orthodontic headgear is a device intended for use with an orthodontic appliance to exert pressure on the teeth from outside the mouth. The headgear has a strap intended to wrap around the patient’s neck or head and an inner bow portion intended to be fastened to the orthodontic appliance in the patient’s mouth.

(b) Classification. Class II.

§ 872.5525 Preformed tooth positioner.

(a) Identification. A preformed tooth positioner is a plastic device that is an impression of a perfected bite intended to prevent a patient’s teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.

(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.


§ 872.5550 Teething ring.

(a) Identification. A teething ring is a device intended for use by infants for medical purposes to soothe the gums during the teething process.

(b)(1) Classification. Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

(2) Class II if the teething ring contains a fluid, such as water.


§ 872.5560 Electrical salivary stimulatory system.

(a) Identification. An electrical salivary stimulatory system is a prescription intraoral device that is intended to electrically stimulate a relative increase in saliva production.

(b) Classification—Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the device design, material composition, and electrical output characteristics are consistent with the intended use;

(2) Any element of the device that contacts the patient must be demonstrated to be biocompatible;

(3) Appropriate analysis and/or testing must validate electromagnetic compatibility and electrical safety, including the safety of any battery used in the device;

(4) Software validation, verification, and hazard testing must be performed; and

(5) Documented clinical experience must demonstrate safe and effective use for stimulating saliva production by addressing the risks of damage to intraoral tissue and of ineffective treatment and must capture any adverse events observed during clinical use.

[80 FR 72586, Nov. 22, 2015]

§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

(a) Identification. Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction.