§ 872.3730 Pantograph.

(a) Identification. A pantograph is a device intended to be attached to a patient’s head to duplicate lower jaw motion.

§ 872.3700 Analog or digital methods.

§ 872.3710 Base metal alloy.

(a) Identification. A base metal alloy is a device composed primarily of base metals, such as nickel, chromium, or cobalt, that is intended for use in fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.

(b) Classification. Class II (Special Controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Dental Base Metal Alloys.'' 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. The device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.190, with respect to general requirements 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 38798, July 25, 2001]

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