§ 872.3740 Retentive and splinting pin.

(a) Identification. A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.

(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. If 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 §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.