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in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3980 Endosseous dental implant accessories.

(a) Identification. Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, and trial abutments.

(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.

[65 FR 60099, Oct. 10, 2000]