Food and Drug Administration, HHS

§ 888.3000 Bone cap.

(a) Identification. A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in

Subpart B—Diagnostic Devices

§ 888.1100 Arthroscope.

(a) Identification. An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

(b) Classification. (1) Class II (performance standards).

(2) Class I for the following manual arthroscopic instruments: cannulas, curettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 888.9.


§ 888.1240 AC-powered dynamometer.

(a) Identification. An AC-powered dynamometer is an AC-powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient’s hand.

(b) Classification. Class II.

§ 888.1250 Nonpowered dynamometer.

(a) Identification. A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient’s hand.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.


Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 888.3000 Bone cap.

(a) Identification. A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in