across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) **Classification.** Class II.

§ 888.3790  
Wrist joint metal constrained cemented prosthesis.

(a) **Identification.** A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) **Classification.** Class II.

§ 888.3810  
Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) **Identification.** A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) **Classification.** Class II.

Subpart E—Surgical Devices

§ 888.4150  
Calipers for clinical use.

(a) **Identification.** A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(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 § 888.9.

§ 888.4200  
Cement dispenser.

(a) **Identification.** A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

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