Food and Drug Administration, HHS

§ 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.

(a) Identification. A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.

§ 888.3670 Toe joint polymer constrained prosthesis.

(a) Identification. A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the first metatarsophalangeal (big toe) joint.

(1) This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) Classification. Class II.

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) Identification. A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) Classification. Class II.


§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

(a) Identification. A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.

(1) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 888.3750 Wrist joint carpal lunate polymer prosthesis.

(a) Identification. A wrist joint carpal lunate prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal lunate bone of the wrist.

(b) Classification. Class II.

§ 888.3760 Wrist joint carpal scaphoid polymer prosthesis.

(a) Identification. A wrist joint carpal scaphoid polymer prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal scaphoid bone of the wrist.

(b) Classification. Class II.

§ 888.3770 Wrist joint carpal trapezium polymer prosthesis.

(a) Identification. A wrist joint carpal trapezium polymer prosthesis is a one-piece device made of silicone elastomer or silicone elastomer/polyester material intended to be implanted to replace the carpal trapezium bone of the wrist.

(b) Classification. Class II.

§ 888.3780 Wrist joint polymer constrained prosthesis.

(a) Identification. A wrist joint polymer constrained prosthesis is a device made of polyester-reinforced silicone elastomer intended to be implanted to replace a wrist joint. This generic type of device consists of a single flexible 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 those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other wrist joint metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.

(a) Identification. A wrist joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device 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