888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.
888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.
888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.
888.3410 Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing
888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.
888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.
888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.
888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.
888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.
888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.
888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.
888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.
888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.
888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.
888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.
888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.
888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
888.3720 Toe joint polymer constrained prosthesis.
888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.
888.3750 Wrist joint carpal lunate polymer prosthesis.
888.3760 Wrist joint carpal scaphoid polymer prosthesis.
888.3770 Wrist joint carpal trapezium polymer prosthesis.
888.3780 Wrist joint polymer constrained prosthesis.
888.3790 Wrist joint metal constrained cemented prosthesis.
888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.
888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

Subpart E—Surgical Devices

888.4150 Calipers for clinical use.
888.4200 Cement dispenser.
888.4210 Cement mixer for clinical use.
888.4220 Cement monomer vapor evacuator.
888.4230 Cement ventilation tube.
888.4300 Depth gauge for clinical use.
888.4540 Orthopedic manual surgical instrument.
888.4580 Sonic surgical instrument and accessories/attachments.
888.4600 Protractor for clinical use.
888.4800 Template for clinical use.
888.5850 Nonpowered orthopedic traction apparatus and accessories.
888.5890 Noninvasive traction component.
888.5940 Cast component.
888.5960 Cast removal instrument.
888.5980 Manual cast application and removal instrument.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 33702, Sept. 4, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 888 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A

manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgical device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html*.

[52 FR 33702, Sept. 4, 1987, as amended at 68 FR 14137, Mar. 24, 2003]

§ 888.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 888.5 Resurfacing technique.

Because of resurfacing techniques, certain joint prostheses require far less bone resection than other devices intended to repair or replace the same