

SECTION IV

REGULATORY HISTORY OF THE DEVICE

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The use of metal/metal hip joint replacement devices predates the Medical Devices Amendments of 1976. Prior to the enactment of these regulations, the FDA chartered the Orthopedic Device Classification Panel to study orthopedic devices and to make recommendations on their classification.

Although the Orthopedic Device Classification Panel was terminated by the FDA in 1978 in favor of reestablishment as the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (The Panel), review of device classification continued. On July 2, 1982, after reviewing the recommendations of the Panel, the FDA issued a Proposed Rule (47 FR 29052) classifying 77 orthopedic devices. Metal/metal hip joint replacement prostheses with cemented acetabular components (CFR 888.3320) and metal/metal hip joint replacement prostheses with uncemented acetabular components (CFR 888.3330) were proposed for class III.

The Final Rule classifying orthopedic devices was published September 4, 1987 (52 FR 33686). Although this formally established metal/metal hip joint replacement prostheses as preamendments class III devices, no date was established for a call for PMAs for these devices. Since that time manufacturers were allowed to market metal/metal semi-constrained total hip joint replacement prostheses via the premarket notification, i.e., the 510 (k) provision of the Act, provided the FDA determined them to be substantially equivalent to preamendments predicate devices. FDA disclosed to applicants filing premarket notifications that data from a clinical trial of the device, or from a similar device, would be required in support of substantial equivalence to a preamendments device.

On April 19, 1994, a memorandum from the Acting Director of the Office of Device Evaluation was released outlining the strategy for implementation of the provision of the Safe Medical Devices Act of 1990 that mandated further activity on these class III devices. This strategy was also published May 6, 1994 (59 FR 23731). Three groups were created regarding these devices:

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| Group 1 | Devices that have fallen into disuse and are unlikely to result in viable PMAs or reclassification petitions; |
| Group 2 | Devices that FDA believed to have a high potential for reclassification; and |
| Group 3 | Devices not at the time considered for reclassification and for which PMAs would be called. |

The memorandum also set forth dates on which the FDA would take various actions on these groups of devices. Metal/metal semi-constrained total hip prostheses (21 CFR 888.3320 and 888.3330) were placed in Group 3 with a call for PMAs scheduled for 1994.

On September 7, 1995 FDA published a Proposed Rule (60 FR 46717 that outlined the date on which PMAs or PDPs for 43 class III devices would be required. The period for written comments closed on January 5, 1995. On September 27, 1996, the Final Rule was published (61 FR 50704) for 41 of the 43 class III devices requiring PMAs or PDPs by December 26, 1996.

The Orthopedic Surgical Manufacturers Association (OSMA) formed seven committees to work on several reclassification petitions for orthopedic devices that were subject to calls for PMAs or PDPs. One of those committees was assigned the responsibility of submitting a reclassification petition for metal/metal semi-constrained total hip joint prostheses. This petition is the result of those efforts.