American Academy of Orthopaedic Surgeons® | AAOS | American Association of Orthopaedic Surgeons®

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December 5, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852
Re: **Docket Number 99P-1864**

Dear Dr. Schwetz:

The American Academy of Orthopaedic Surgeons (Academy), representing over 16,000 Board certified orthopaedic surgeons, is pleased to express our support for the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from Class III to Class II. This device was listed in the proposed rule notice "Orthopaedic and Rehabilitation Devices: Reclassification of the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" in the Federal Register published on September 6, 2001 [Docket No.99P-1864].

We share the concerns of FDA in ensuring that safe and effective products enter the marketplace. We remain committed to protecting consumers and our patients, as well as encouraging that the latest technologies in safe orthopaedic devices come to the marketplace through a least burdensome, streamlined regulatory review.

The orthopaedic clinical and research community has worked closely with the Orthopaedic Surgical Manufacturers Association (OSMA) to develop the petition in support of the reclassification of the device, which was formally submitted to the FDA in June 1999. Many Academy fellows provided clinical expertise to assemble the supporting data for this reclassification petition. We believe that these data represent the best clinical evidence to date to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint orthopaedic device from Class III to Class II.

Since the classification of constrained devices into Class III under the 1976 Medical Device Amendments, the development of devices and surgical techniques has proffered a considerable amount of peer-reviewed clinical publications. These current data support the safety and efficacy of these devices.

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The data supplied in OSMA's petition for reclassification demonstrate that the special controls required to be met under a Class II designation, along with general controls, provide reasonable assurance of the safety and effectiveness of the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint.

We commend the FDA in its decision to reclassify this orthopaedic device, and we look forward to continuing to work with you in the future in the reclassification of other orthopaedic devices for which we believe clinical data support their designation as Class II devices.

Thank you for your actions in this matter.

Sincerely,

William W. Tipton, Jr., MD
Executive Vice President

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