



American Academy of  
Orthopaedic Surgeons®

AAOS

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Orthopaedic Surgeons

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June 5, 2000

Jane E. Henney, MD  
Commissioner  
Food and Drug Administration (FDA)  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Dr. Henney:

The American Academy of Orthopaedic Surgeons (Academy), representing over 16,000 Board certified orthopaedic surgeons, is pleased to take this opportunity to express our support for the reclassification of the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis postamendment Class III orthopaedic medical devices. These devices were listed in the notice of panel recommendation in the Federal Register that was published on March 7, 2000. [Docket No.00N-0018].

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, while at the same time making sure that the latest technologies in safe orthopaedic devices come to the marketplace through 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 these two orthopaedic devices, which were formally submitted to the FDA in July 1997. Many Academy Fellows provided balanced expertise and clinical experience to assemble the supporting data for these reclassification petitions. We believe that these data represent the best clinical evidence to date to support the reclassification of these devices from Class III to Class II.

Porous coated technology has been previously approved by the FDA for biological fixation of knee devices. Additionally, several thousand knees of various designs from multiple orthopaedic device manufacturers are implanted each year with either partial cement or without cement fixation. Known risks can be controlled either clinically or through the design of the device. Moreover,

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peer-reviewed journals document clinical experiences from long-term studies. Current data support the safety and efficacy of these devices.

The Orthopaedic and Rehabilitation Devices Panel voted to reclassify both devices in a public meeting on January 12-13, 1998. Prior to that meeting, the FDA identified special controls to include eleven consensus standards from the American Society of Testing and Materials, in addition to four FDA guidance documents. These special controls in addition to general controls reasonably assure the safety and effectiveness of both knee devices.

It is appropriate that the knee joint patellofemoral metal/polymer porous-coated uncemented prosthesis and the knee joint femoral (uni-compartmental) metal/polymer porous-coated uncemented prosthesis now be reclassified as Class II devices.

We commend FDA in its decision to reclassify these orthopaedic devices, 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,

A handwritten signature in black ink that reads "William W. Tipton, Jr." with a stylized flourish at the end.

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

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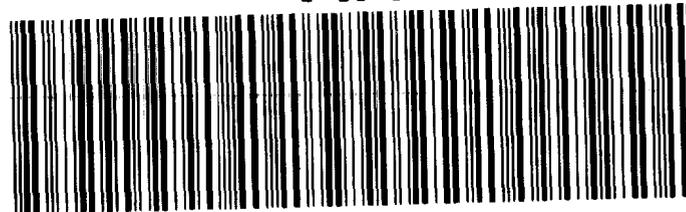
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