



American Academy of Orthopaedic Surgeons®

AAOS

American Association of Orthopaedic Surgeons®

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May 3, 2002

Lester R. Crawford, Jr., DVM, PhD  
Deputy Commissioner  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: **Docket No. 01 N-041 1**

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Dear Dr. Crawford:

The American Academy of Orthopaedic Surgeons (AAOS), representing over 18,000 Board certified orthopaedic surgeons, is pleased to express our support for the reclassification of the resorbable calcium salt bone void filler intended to fill bony voids or gaps, caused by trauma or surgery, that are not intrinsic to the stability of the bony structure from Class III into Class II (special controls). This proposed reclassification was published in the proposed rule notice "Orthopaedic Devices: Proposed Classification for the Resorbable Calcium Salt Bone Void Filler Device" in the February 6, 2002 Federal Register [Docket No. 01 N-041 1].

Calcium sulfate bone void fillers have amassed a remarkable record of safety and a long history of use to fill bone defects of traumatic, surgical and disease origin. The AAOS believes that the special controls required to be under a Class II designation, along with general controls, provide reasonable assurance of the safety and effectiveness of the resorbable calcium salt bone void filler device.

The AAOS shares 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.

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

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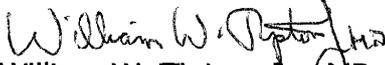
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reclassification of other orthopaedic devices for which we believe clinical data support their designation as Class II devices.

Thank you for your actions in this matter.

Sincerely,

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

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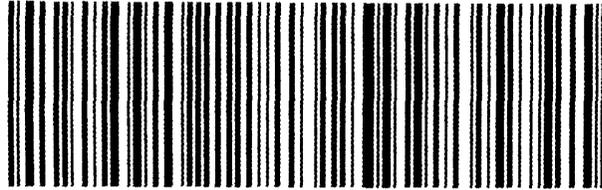
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