NORTH AMERICAN SPINE SOCIETY

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21st ANNUAL MEETING
September 26-30, 2006
Seattle

April 19, 2006

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852.

Re: Docket Nos. 2006N-0019 / 2006D-0020
Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device /
Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

The North American Spine Society (NASS) is a 4000 plus member medical specialty society representing orthopedic surgeons, neurosurgeons, physiatrists, pain management specialists, radiologists, chiropractors, nurses, nurse practitioners, physical therapists, psychologists, researchers and others dedicated to the multidisciplinary approach to spine care. NASS is encouraged by the work being done by the Food and Drug Administration (FDA) to improve the quality of care for patients and shares this dedication to ensuring the best possible care for spine patients.

On behalf of NASS, I would like to take this opportunity to thank the FDA for the opportunity to comment on the proposed downclassification of intervertebral body fusion devices (cages) that contain bone grafting materials from Class III (premarket approval) to Class II (special controls). Given the prolific evidence cited by the FDA to support the downclassification of these cages and the content of the draft guidance document developed as the special control to help ensure the safe and efficacious use of these devices, NASS supports the downclassification of intervertebral body fusion devices and the special controls identified in the guidance document.

As the FDA works diligently to assess the safety and efficacy of spine interventions, NASS would like to voice concern about the current practice whereby device manufacturers circumvent submission of a premarket application (PMA) by submitting a 510(k) application on the basis of substantial equivalence for devices which are, by no means, substantially equivalent to the predicate device. For example, a device manufacturer's 510(k) application was approved for interbody spacers, on the basis of substantial equivalence to femoral distal cement restrictors. These two classes of devices are by no means substantially equivalent. While we understand the difficult task of the FDA's Orthopedic and

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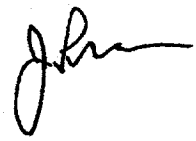
Restorative Devices Panel, NASS remains concerned about the unintentional consequences of allowing manufacturers to continue petitioning for and obtaining 510(k) approval based on substantial equivalence when two devices being compared are in no way intended for equivalent usage.

In our letter of December 7th to Mark Melkerson, MS, Acting Director of the Division of General, Restorative and Neurological Devices, NASS extended to the FDA an offer to collaborate with the FDA and provide the expertise of our membership. Our Multidisciplinary Patient Care Committee and others within NASS have expressed great interest in collaborating with the FDA to provide input on study design methodology for postmarket surveillance projects and any other opportunities where the experience and knowledge of highly qualified, experienced spine care providers would be helpful to the FDA.

We are currently training our committee members in evidence analysis and plan to expand this training to our general membership over the next several years. When you combine this with our multidisciplinary nature and practical experience in the field, our membership is uniquely qualified to critically assess study design and methodology, and could be of much value to the FDA.

Again, I would like to thank the FDA for the opportunity to comment and to commend you on your efforts to help ensure the delivery of safe and efficacious interventions to spine patients. NASS welcomes the opportunity to assist the FDA, and urges you to contact NASS with any questions related to spine care. Please do not hesitate to contact me at NASS through Belinda Duszynski, Research Manager, at (815) 444-8611 or duszynski@spine.org, if we can be of assistance.

Sincerely,



Joel M. Press, MD
President

Cc: NASS Board of Directors
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