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April 6, 2006

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

RE: Docket No. 206N-0019, Reclassification of the Intervertebral Body Fusion Device.

Dear FDA:

The Orthopedic Surgical Manufacturers Association (OSMA) would like to express its full support for the reclassification of the Intervertebral Body Fusion Device as stated in the Proposed Rule and published in the Federal Register / Vol. 71, No 27 / Thursday, February 9, 2006. No changes are requested to either the Rule or the *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*.

The Orthopaedic and Rehabilitation Devices Panel met on Thursday, December 11, 2003 to make a recommendation to the Food and Drug Administration on the FDA-proposed reclassification of the intervertebral body fusion device. This FDA-proposed reclassification was supported by OSMA at the meeting. The Panel voted unanimously to recommend that FDA reclassify the device into Class II. Despite the unanimous support of the Panel, and support from FDA and private industry, it has taken more than two years to publish the proposed rule. OSMA would appreciate every effort to expedite the final publication of this reclassification rule.

The reclassification language is not specific regarding design, materials or treatment levels of the spine. OSMA member companies encourage FDA to consider the Least Burdensome Provisions of the FDA Modernization Act of 1997 and limit the burden of clinical data requested to establish equivalence under this rule.

OSMA is a trade organization whose membership consists of manufacturers of orthopedic surgical appliances, implants, instruments, medical equipment and orthobiologics. All the companies that currently hold PMAs for intervertebral body fusion devices are OSMA members. Since its inception in 1954, OSMA has actively participated in standards development, patient education, product labeling guidelines, international activities and has supported multiple reclassification petitions. Cooperation and interaction with FDA and health care professionals on issues that appropriately lessen the regulatory burden and improve the application of device law continue to be major OSMA objectives.

OSMA would like to thank the Panel and FDA staff involved in this reclassification effort and to especially recognize FDA staff member Jodi Anderson for her diligence with this project. We look forward to the expeditious publication of the final rule.

Regards,

Sally L. Maher
President

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