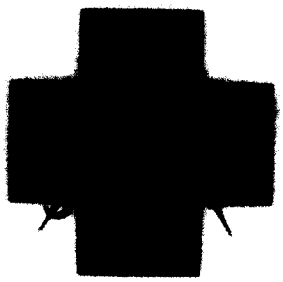

December 6, 2006

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

RE: Docket 2006P-0334, Reclassification Petition for Bone Heterografts

Dear FDA:

The Orthopedic Surgical Manufacturers Association (OSMA) would like to express its full support for the reclassification of bone heterografts as proposed by Regeneration Technologies Inc. (Docket 2006P-0334). We believe that the Class II 510(k) pathway will assure the most appropriate level of regulatory control necessary to ensure the safety and effectiveness of bone heterograft used in the spine. The current Class III designation is no longer appropriate because of the existing standards and guidance documents currently available for spinal systems and animal-derived devices.

FDA has historically reserved Class III for new technologies and high risk devices, neither of which are relevant to the use of bone heterograft in the spine. Safety of the material can be established through ISO 10993 biocompatibility testing and standard biomechanical testing methods are appropriate to verify device performance. We propose that material composition alone should not drive interpretations and decisions concerning the proper scope of spinal classification regulations. Other spinal device regulations suggest that functionality and intended use should be used as the primary basis for device classification.

In light of these considerations OSMA encourages FDA to apply the "least burdensome" principles of the Food and Drug Administration Modernization Act of 1997 in assessment of the bone heterograft reclassification petition.

OSMA is a trade organization whose membership consists of manufacturers of orthopedic surgical appliances, implants, instruments, medical equipment and orthobiologics. Since its inception in 1954, OSMA has actively participated in standards development, patient education, product labeling guidelines, and 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 FDA for the opportunity to comment on this reclassification petition.

Regards,

Sally L. Maher
President

2006P-0334 C1

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