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June 5, 2007

Document Mail Center (HFZ-215)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20857

Re: Docket 2006P-0334/CCP 1
Reclassification Petition for "Bone Heterograft", C.F.R. 888.3015

Dear Ms. Sloan:

We have considered your advice regarding a new indications statement for the Bone Heterograft reclassification petition. We propose that the current indications be replaced by the following statement in order to more clearly define the product's intended use:

Bone heterografts are indicated for use in the cervical spine to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. Bone heterografts are also indicated for treating fractures of the cervical spine and may be used with bone graft materials. Bone heterografts may be load bearing or may require the use of supplemental fixation.

If you have additional questions on this matter please feel free to contact me directly. Thank you for your work on this petition.

Sincerely,

Lisa C. Simpson

Lisa C. Simpson
Director, Regulatory Affairs

2006 P-0334

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