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June 12, 2003

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir or Madam:

Subject: Reclassification Petition for Mobile Bearing Knees

Enclosed are five (5) copies of a petition requesting reclassification for Mobile Bearing Knees by the FDA from Class III to Class II. This petition is being submitted by the Orthopedic Surgical Manufacturers Association (OSMA) under 21 CFR part 513(e).

If you require any additional information or have any questions, please contact the undersigned by telephone at (901) 867-4704.

Sincerely,

Robert W. Churinetz

Robert W. Churinetz
Vice President, OSMA

Enclosures

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ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
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Petition for Reclassification

Mobile Bearing Knees

Submitted by:

The Orthopedic Surgical
Manufacturers Association

Date: June 12, 2003