

MEMORANDUM**C O V E R P A G E**

TO: The Orthopedic and Rehabilitation Devices Advisory Panel (the Panel)

FROM: Biomedical Engineer / Lead Reviewer
FDA/ODE/DGRND/Orthopedic Devices Branch

DATE: May 26, 2004

SUBJECT: Summary of attached information regarding OSMA's reclassification petition for the post-amendments Class III Mobile Bearing Knee.

We are asking you to come to this meeting for the purpose of giving FDA recommendations regarding the reclassification petition submitted by the Orthopaedic Surgical Manufacturer's Association (OSMA) to reclassify mobile bearing knees from Class III (premarket approval) to Class II (special controls). This petition involves the reclassification of two general types of mobile bearing knee prostheses (total and unicompartmental). It should be made clear that this is a petition for reclassification only; no products are being evaluated for approval.

This package contains the following information:

1. Copies of the FDA review memos regarding this petition
2. A copy of the 2/18/04 FDA deficiency letter
3. Questions to consider during your review
4. Slides summarizing the reclassification process
5. A copy of the panel classification questionnaire (to be filled out at the meeting)
6. A copy of the recent National Institutes of Health (NIH) Consensus Statement on Total Knee Replacement - (provided as a primer on the current state of total knee replacement)
7. A copy of the original petition and amendment

Volume 1 of the petition (Panel Document 1) includes a hard copy of the original reclassification petition (dated June 12, 2003), minus the references. A table of contents and bibliography are included. On the back page of the volume is a CD-ROM that contains the entire petition and all references in electronic format. Volume 2 of the petition (Panel Document 2) includes a hard copy of an amendment to the petition (dated March 31, 2003) submitted in response to FDA deficiencies. Again, a CD-ROM with an electronic version of the entire amendment is included on the back page of the volume.

The central issue for you to consider is whether the data within this petition supports the reclassification of the specified mobile bearing knee prostheses into Class II (special controls),

and whether adequate special controls are available to address the risks identified for these device types.