

## SECTION XII – CONCLUSION

OSMA believes that the information presented in this petition amply justifies the reclassification of mobile bearing knees, both tricompartmental and unicompartmental metal/polymer mobile bearing cemented or porous coated uncemented prostheses, from Class III to Class II. Sufficient evidence now exists that the mobile bearing knees, as a class of devices, are comparable in safety and efficacy to Class II fixed bearing knees. The risks associated with mobile bearing knees can be defined and mitigated, and the Special Controls necessary for the FDA to regulate these knee prostheses as Class II devices are adequate to provide reasonable assurance of safety and efficacy.

In support of these assertions, several key points made within this petition are summarized below.

- Test data from peer-reviewed journals indicates that polyethylene wear rate is lower in mobile bearing knees compared to fixed bearing. Kinematics of mobile bearing knees are similar to those of fixed bearing knees. Neither mobile nor fixed bearing knees exactly replicate the motion of the normal knee, but both provide good functional stability and mobility. (see Section VI)
- Data provided by sponsors of seven ongoing controlled clinical trials (IDE studies) suggests that clinical performance of these seven designs is comparable to that of fixed bearing knees. Of particular note, the excellent clinical outcomes from the Oxford Meniscal Bearing Unicompartmental Knee - Phase II provide evidence of significant evolution in unicompartmental design and surgical technique since early designs. (see Section VII)
- Data from two international clinical outcomes studies provide robust evidence of the clinical success of mobile bearing knees in general usage. These data sets represent a variety of surgical skills among numerous surgeons, in numerous countries, from general patients not limited by inclusion/exclusion criteria. Currently, 2 year data is available from a total of 243 patients, but the total enrollment in the two clinical studies is over 1650. To date, both studies reveal excellent clinical success. (see Section VII)
- A meta-analysis comparing the clinical performance of many types of mobile bearing knees is presented. It shows that various types of mobile bearing knees, including rotating platform, meniscal bearing, cemented and cemented, PCL-retaining or sacrificing, with varying degrees of conformance and types of motion, as a group, provide clinical outcomes similar to those of fixed bearing knees. (see Section VIII)

- A meta-analysis comparing survivorship of mobile bearing versus fixed bearing knees shows that mobile bearing knee survivorship is not statistically different from that of fixed bearing knees. They both have satisfactory long-term survivorship of greater than 90 percent. (see Section VIII)
- Risks associated with mobile bearing knees are well understood, and can be mitigated to levels that provide an acceptable risk/benefit ratio. Risks can be successfully regulated by the Special Controls proposed. (see Section X)
- Mobile bearing knee design has matured considerably in the approximately 25 years since the first designs were released. As documented, there is a wide variety of mobile bearing knees on the market internationally. Approximately 46 different designs are being implanted into thousands of patients. In the U.S., there are five mobile bearing knee designs on the market with successful clinical history. (see Section XI)
- Finally, a number of orthopedic surgeons are on record, expressing their desire to include mobile bearing knees in their list of treatment options, particularly for younger patients. They believe that their knowledge of the risks associated with mobile bearing knees, and the established clinical success of knees currently available in the United States, argue that these devices are ready to be reclassified. They look forward to expedited technical development of mobile bearing knees following reclassification. (see Appendix 1).

The sponsors conclude that Special Controls available to the FDA will allow them to regulate mobile bearing knees to the statutory requirement of *reasonable assurance* of safety and efficacy. Reclassification from Class III to Class II will allow more rapid development of mobile bearing knees, and will provide surgeons and patients with attractive alternatives in knee replacement.