

SECTION V - BASIS FOR PETITION

This document is a petition for reclassification of the following devices from Class III to Class II:

- "Knee joint patellofemorotibial metal/polymer mobile bearing cemented or porous-coated uncemented prosthesis" and
- "Knee joint femorotibial (uni-compartmental) metal/polymer mobile bearing cemented or porous coated uncemented prosthesis"

When the first mobile bearing knee (mbk) was introduced into the U.S. market (DePuy Orthopedics, Inc.), there was no pre-amendment device nor an existing Class II knee device to support a Substantial Equivalence determination. As a result, the mobile bearing knee was automatically classified as a Class III device (Pre-Market Approval Application (PMA) required), under Section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act").

This petition is submitted in accordance with Section 513(e) of the act which allows device reclassification if the FDA finds that the requirements of Class III are "not necessary to provide reasonable assurance of its safety and efficacy". Information presented in this petition is intended to establish that a sufficient body of evidence now exists to justify reclassification, and that the controls established for Class II devices are sufficient to provide *reasonable assurance* of safety and efficacy. Class II controls include General Controls plus Special Controls such as performance standards, postmarket surveillance, patient registries, guidelines, recommendations, or other actions deemed necessary by the FDA.

Evidence presented in this petition includes:

- Summary of testing of numerous mobile bearing knee designs published in scientific literature (see Section VI).
- Unpublished clinical data: information derived from IDE studies and international clinical outcomes studies (see Section VII).
- Published clinical data: summaries of published clinical studies, a meta-analysis of patient outcomes following mbk replacement and a meta-analysis of survivorship of mobile versus fixed bearing total knee replacement (see Section VIII).
- A summary of adverse events reported to the FDA as Medical Device Reports (MDRs) (see Section IX).
- A risk analysis for mbks, and a listing of proposed means of controlling risks (see Section X).
- A list of mbk prostheses currently or previously available in the U.S. and worldwide (see Section XI).

This information supports the conclusion that mbks are as safe and effective as fixed bearing knees, which are currently designated as Class II devices. In the 25 years since the first mbk, these prostheses have evolved through several design generations, and today present an effective alternative to fixed bearing knees. Reclassification of mbks will open the door to more rapid design evolution, with the promise of even greater polyethylene wear reduction, and more normal kinematics.

Also included in this petition are "Letters in Support of the Downclassification Petition on Mobile Bearing Knee Implants" (Appendix 1). These letters are voluntary expressions of support by leading orthopedic surgeons, explaining why they want to have the option of mobile bearing knees in their armamentarium. They urge the reclassification of these devices.