

SECTION I - INTRODUCTION

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"

This petition is being submitted in accordance with Section 510(e) of the Federal Food Drug and Cosmetic Act and is organized in accordance with 21CFR Part 860 Subpart C - Reclassification, §860.123 Reclassification petition - Content and form.

The sponsor of this petition is the Orthopedic Surgical Manufacturers Association (OSMA). OSMA is a trade organization whose membership consists of manufacturers of finished surgical appliances, devices, biological products, instruments, or equipment used in the treatment of orthopedic pathologies. Several OSMA member companies manufacture mobile bearing knees and have contributed clinical data or other information to this petition.

While there are many types of knee prostheses, and many ways to categorize them, one of the broadest classifications is the distinction between fixed bearing and mobile bearing knees (mbks). A fixed bearing knee most commonly consists of a metal tibial tray to which a polyethylene tibial articulating surface is permanently affixed in a stationary position. A metal femoral component articulates with the fixed polyethylene surface. In contrast, the defining feature of a mbk is the presence of a moving polyethylene bearing that articulates with both the femoral condyle and the tibial tray.

Fixed bearing knees typically face an intrinsic "kinematic conflict" between the need for dispersing contact forces over a greater range of the polyethylene surface in order to reduce wear, and the reduction in mobility that results from the more highly conforming polyethylene. Mobile bearing knee designs utilize a highly conforming surface that disperses contact forces over a large area, thus potentially reducing wear. The design simultaneously incorporates mobility in the polyethylene bearing, which reduces implant-to-bone interface stresses. This may prevent implant loosening, which has been attributed to high interface stresses in highly conforming fixed bearing knee designs. The clinical data presented in this petition indicate that mbks have evolved over the past 25 years, and that the recent generation of mbks function as successfully as most fixed bearing knees.

The first mbk designs were introduced in the late 1970's. The Oxford Unicondylar knee (Biomet, Inc., Warsaw, IN) was the first to utilize a mobile bearing to reduce contact stress while also reducing implant-to-bone interface stress. Since those early implants, several generations of mbks have followed, and today there are nearly 50 implant designs

on the international market. These include unicondylar and bi-condylar knees, with either platform-style or meniscal bearing design of the polyethylene articulating surface. There are numerous variations in the directional mobility of the polyethylene, type of constraint of the polyethylene, and treatment of the PCL. Mobile bearing designs currently on the market are highly successful, as documented in numerous publications of clinical results found in peer-reviewed journals.

In the United States, mobile bearing knees have been classified as Class III. This is because regulation stipulates that devices which were not in existence prior to the Medical Device Amendments of the Federal Food, Drug and Cosmetic Act (1976), or for which there is no existing Class II device to support a Substantial Equivalence determination are automatically designated as Class III. The first mobile bearing knee to be approved by the FDA for sale in the U.S. was the Low Contact Stress (LCS) Rotating Platform Knee (J&J DePuy, Warsaw, IN). PMA approval for this knee was received in 1985, and since then four other mobile bearing knees have been approved in the U.S. (see Section XI).

Reclassification of several types of knees from Class III to Class II was considered by an FDA Advisory Panel on January 13, 1998 ("Petition for Reclassification, Patello-Femoral-Tibial Metal/Polymer/Metal/Polymer/Metal Biologically Fixed Prosthesis, submitted by the Orthopedic Surgical Manufacturers Association, July 25, 1997). Mobile bearing knees were included in that petition. At that time, the Panel believed there was insufficient evidence to provide reasonable assurance of safety and efficacy for the entire class of mobile bearing knees. They recommended reclassification only of tricompartmental mobile bearing knees that are cemented and have a rotating/translating base. However, they recommended the retention of Class III designation for all other tricompartmental and unicompartmental mobile bearing knees. The FDA subsequently chose to recommend submission of a new reclassification petition for the entire class of mobile bearing knees, rather than reclassify specific subcategories.

In the years since this Panel recommendation, a large amount of data has accumulated which now provides strong evidence of the clinical success of numerous mbk designs. Presented in this petition are:

- A summary of test results on wear, kinematics, and biomechanics from more than 45 articles published in peer-reviewed journals (see Section VI);
- A summary of unpublished clinical data from seven on-going IDE studies and two large international clinical outcomes studies (see Section VII);
- A summary of published clinical data from more than 50 articles published in peer-reviewed journal articles, together with a meta-analysis comparing clinical outcomes for different mbks and a meta-analysis comparing survivorship of mbks versus fixed bearing knees (see Section VIII);
- A listing of adverse events reported through the FDA's Medical Device Reporting (MDR) system (see Section IX);
- A Risk Analysis, suggested special controls, labeling, and tests and test methods (see Section X);

- A list of mbks currently or previously on the market, including 46 devices that are available internationally, five of which are also available in the U.S. (see Section XI).

The sponsor believes that this information provides strong evidence of the safety and efficacy of mobile bearing knees, and that the risks associated with these devices are now adequately defined. Therefore, reclassification from Class III (Premarket Approval Application) to Class II (Special Controls) is justified. The FDA can regulate these devices adequately under Class II Mechanisms of General Controls (e.g. Establishment Registration and Device Listing, Good Manufacturing Practice, Labeling, Premarket Notification, Medical Device Reporting) and Special Controls (e.g. performance standards, postmarket surveillance, guidelines, recommendations, etc.).