SECTION V

BASIS FOR PETITION

This document is the second petition sponsored by OSMA for reclassification of metal/metal, semi-constrained total hip prostheses, cemented or uncemented, from class III to class II. Sufficient evidence now exists to address the risks cited in the July 2, 1982 Proposed Rule (Ref. 47 FR 29052) that originally led to placement of these devices into class III and the concerns of the Orthopedic and Rehabilitation Devices Panel and FDA. In the Proposed Rule, FDA commented that insufficient clinical experience existed to fully establish the persons for whose use the devices are intended and proper conditions of use. Because of the lack of available adequate data to demonstrate the safety and efficacy of these devices, FDA believed that there is insufficient valid scientific evidence to determine that special controls, in addition to the general controls applicable to all devices, would provide reasonable assurance of the device's safety and effectiveness for their intended uses.

Published and unpublished information, both in the U.S. and Europe, since the original classification of these devices by FDA now provides sufficient proof of the safety and efficacy these designs to the degree that risks to patients can be adequately controlled by class II controls. This evidence, provided in the following sections and appendices of this petition, consists of a summary report of the testing of metal/metal hip designs from the medical and scientific literature (Section VI.- Summary of Testing), Section VII.- Published/Unpublished Clinical Results of Metal/Metal Hips provides a summary report of the data from long term regulated prospective multicenter clinical trials of metal/metal semi-constrained total hip prostheses conducted in the U.S. in the form of a survival analysis and a summary of the published clinical outcomes. There is also a report in that same section from an independent expert on short and long term biological effects of metal-on-metal total hip replacement from human retrieval and in-vitro studies. Also included is a summary of the adverse events reported to the U.S. and reported in the published literature (Section VIII.- Medical Device Reports (MDRs). Another section assesses the known risks to patients imposed by these devices and how these risks can be adequately controlled via the pre-clinical testing, labeling and other regulatory requirements imposed on class II devices (Section IX.- Regulatory Control of Risks).

Metal/metal hip prostheses benefit public health by making devices generally available that significantly reduce the potential for failure of the prosthetic implant from wear and/or loss of fixation as a result of adverse bone remodeling caused by generated wear debris. This reclassification petition contains sufficient evidence that the risks imposed by these devices are not greater than those for metal/polymer semi-constrained hip prostheses and can be adequately controlled by the means available to FDA under class II. This conclusion is based upon, and supported by, the reports appearing in the scientific literature regarding the reduced wear afforded by these designs, the results of the clinical use of these devices reported in this petition and in published articles, the low frequency of adverse events reported from the use of these devices and the availability of recognized standards for ensuring the use of the optimal available implant materials.