

SECTION I
INTRODUCTION

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This document is a petition for reclassification of the following devices: Metal/metal, semi-constrained total hip prostheses, cemented or uncemented, from class III to class II.

This petition is being submitted in accordance with Section 513(e) of the Act and organized with respect to its form and content in accordance with 21 CFR Part 860, Subpart C- Reclassification 860.123.

The sponsor of this petition is the Orthopaedic Surgical Manufacturers Association (OSMA). OSMA is a trade organization whose membership consists of manufacturers of orthopaedic surgical appliances, implants, instruments, and equipment. The majority of the companies that manufacture semi-constrained, metal/metal hip prostheses, the subject of this petition, are represented in OSMA.

Total hip joint replacement prostheses are devices used to permanently replace the articulating surfaces of the hip joint in cases where they have been damaged by trauma or disease. A metal/polymer semi-constrained total hip replacement prosthesis consisting of a metal acetabular shell with a polymer liner coupled with a metal hip femoral component is a class II device. Semi-constrained metal/metal total hip prostheses are preamendments class III devices. This type of hip prosthesis is used for similar general indications and bears risks similar to the semi-constrained, metal/polymer hip prosthesis.

The significant difference between the metal/polymer hip design and the metal/metal hip designs is the articulating surface of the acetabular liner component. For the metal/polymer hip prosthesis design, the femoral prosthesis articulates with an acetabular liner component manufactured from a polymeric material, most commonly ultrahigh molecular weight polyethylene. Whereas the metal/metal hip designs employ acetabular liners manufactured from metal alloys such as cobalt chromium molybdenum for this same purpose.

Semi-constrained metal/metal hip prosthesis designs have been employed previously and were, in fact, the original hip prosthetic designs predating the Medical Device Amendments of 1976. At the time of initial classification of orthopaedic devices, the Classification Panel (The Panel) believed that sufficient information existed regarding the known risks for metal/metal hip designs and that these risks could be adequately controlled through, among other things, the development of a performance standard. Therefore, the Panel recommended to FDA that these devices be classified into class II. FDA disagreed with the recommendation of the Panel and believed that insufficient clinical experience existed to fully establish the persons for whose use the devices are intended and the proper conditions of use. Because of the lack of available adequate data to demonstrate the safety and efficacy of these devices, FDA believed that insufficient

information existed to support the conclusion that general controls or performance standards will provide reasonable assurance of safety and effectiveness and proposed that these devices be classified into class III. Since that time refinements in prosthetic design and improvements in manufacturing processes, coupled with increased understanding of the modes for failure have significantly reduced the potential for failure experienced with earlier metal/metal semi-constrained hip prostheses. It should be noted, however, that a large number of these early metal/metal designs have functioned successfully for long periods.

The sponsor believes that the existing clinical and scientific literature and the results reported from clinical studies of metal/metal semi-constrained hip prostheses conducted under U.S. FDA Investigational Device Exemption (IDE) regulations and the European Medical Device Directive (MDD) provide sufficient safety and efficacy information to adequately define the risks associated with these devices. Therefore, FDA's statutory authority under Labeling, Premarket Notification, Good Manufacturing Practices, and Special Controls is sufficient to regulate metal/metal semi-constrained hip prostheses as class II devices.

Detailed information in support of this request is presented in the subsequent sections of this petition. Section II describes the type of devices for which reclassification is requested. Section III discusses the current CFR classification description for this device type and provides proposed descriptions and the proposed regulatory classification for these devices. Section IV describes the regulatory history of the device. Section V discusses the basis and rationale for the petition. Section VI is a summary of the literature for testing performed on metal/metal hip prostheses articulations. Section VII summarizes the published clinical results and the clinical results from multicenter, prospective clinical trials of metal/metal semi-constrained hip prostheses. Section VIII addresses the medical device and vigilance reports for these devices. Section IX defines the risks of metal/metal semi-constrained hip prostheses as reported in the literature and describes how class II regulatory authority may be applied to control these risks. Section X discusses availability of metal/metal hip designs and lists those devices currently and previously marketed. Section XI is a brief conclusion.