

SECTION I

INTRODUCTION

This document is a petition for reclassification of a constrained metal/polymer hip prosthesis, cemented or uncemented, from class III to class II.

This petition is submitted under Section 515(1) (21 USC 360e(i)) with specific reference to FDA's "515(i) Order" of August 14, 1995, which required the submission of safety and effectiveness information for various preamendment class III devices. The information in this submission is organized in accordance with that Order, rather than with the formal reclassification procedure of 21 CFR 860.123.

The sponsor of this petition is the Orthopedic Surgical Manufacturers Association (OSMA). OSMA is a trade organization whose membership consists of manufacturers of orthopedic surgical appliances, implants, instruments, and equipment. The majority of the companies that manufacture constrained 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 disease. A metal/polymer semi-constrained total hip joint replacement prostheses consisting of a metal acetabular shell with polymer liner coupled with a metal hip femoral component is a class II device. The constrained metal/polymer device (preamendment class III) consists of a similar metal acetabular shell with a polymer liner coupled with a metal hip femoral component. Both the semi-constrained (class II) and the constrained (class III) hip prostheses are used for similar general indications and bear similar risks.

The only significant difference between the semi-constrained and constrained devices is the degree of constraint of the polymer acetabular liner. The constrained liner retains the ball of the femoral component to stabilize the joint and resist dislocation. It is used to treat patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, intraoperative instability, and/or neuromuscular ~~disease~~. The semi-constrained liner relies on the **soft** tissue in the hip joint to stabilize the joint

Such arthroplasty procedures have been performed for many years, predating the Medical Device Amendments of 1976. Nevertheless, at the time of initial classification, the Classification Panel felt there was insufficient clinical information available on risks associated with the constrained devices available at that time, and these devices were, therefore, placed in class III. Since that time, the development of devices and surgical technique has

continued, and a considerable quantity of published clinical results have appeared in the peer-reviewed literature. This body of "new information" provides the grounds for the present petition.

The sponsor believes that the presently-existing clinical literature provides sufficient safety and efficacy information to adequately define the risks associated with the device, and that FDA's statutory authority under Labeling, Premarket Notification, Good Manufacturing Practices, and Special Controls is sufficient to regulate 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 descriptions for this device. Section IV describes the regulatory history of the device. Section V discusses the basis and rationale for the petition. Section VI summarizes the clinical results of constrained hip arthroplasty as documented in the literature, and unpublished results. Section VII defines the risks of constrained hip arthroplasty based on the literature reports. Section VIII shows how class I regulatory authority may be applied to control these risks. Section IX requests the proposed reclassification include the use of any legally-marketed metal acetabular shell and femoral component with a constrained polymer liner, including porous-coated shell intended for uncemented use. Section X is a brief conclusion.