SECTION II

DEVICE INFORMATION

The following describes the devices for which reclassification is being sought.

A. General Device Description and Use

1. General

Total hip prostheses are orthopaedic reconstructive devices intended to replace the principal articulating surfaces of the hip joint where these surfaces are not present or have been severely damaged by inflammatory or degenerative joint disease or by traumatic injury. The main objectives of this surgery are relief of pain and restoration of function.

Total hip replacement surgery using metal/metal hip prostheses is no different than using metal/polymer hip prostheses. The difference is the use of a metal alloy insert versus a polymeric (polyethylene) insert in the acetabular component for articulation with the femoral prosthesis component. The alloy insert used in the metal/metal designs has a highly polished surface finish and is manufactured to a precision tolerance. The use of articulating surfaces made from certain types of metal alloys has been shown to reduce the amount of wear and deformation as compared to polyethylene inserts used for this same purpose.

Total hip prostheses generally consist of two components, a femoral component and an acetabular component. Either of these components can be modular in design (e.g. a taper-fit femoral head and a metal acetabular shell with an insert liner). The femoral component is intended to replace the head of the femur, and its stem is inserted into the medullary canal of the femur to anchor it. Femoral components are manufactured from alloys such as cobalt-chromium-molybdenum or titanium-aluminum-vanadium. Femoral components may be fabricated as a single piece (head-stem) or they may be modular with separate head and stem components having a variety of head diameters/neck lengths that can be fitted to a stem of a chosen size. Modular femoral components are generally fitted together by Morse taper connections. Femoral stems may be cemented or press-fit into the medullary canal of the femur. The spherical femoral head is designed to articulate with the acetabular component that is fixed into the prepared acetabulum.

The metal/metal acetabular component can either be a one-piece design or a modular design. For one-piece metal designs, the entire component can be fabricated from a single piece or it may have a metal insert that is permanently welded to the metal outer shell. One-piece metal and polyethlyene component designs have a construct consisting of a polyethylene outer shell that is molded to the metal insert which is then secured to a metal outer shell.

The modular acetabular designs consist of either a metal insert component that is secured to the metal outer shell by means of a Morse taper, or a polyethylene component that is molded to a metal insert which is then secured to the metal outer shell by means of a mechanical interlock. The acetabular components are manufactured in a variety of sizes and inner diameters to meet the anatomical needs of patients. They are secured to the prepared acetabulae employing different fixation methods including bone screws, spikes, fins, threads, bone cement, and/or porous coatings for biological fixation. (Porous coated, semi-constrained hip prostheses intended for use without bone cement were reclassified from class III to class II by the FDA in 1994)

Hip prostheses recommended for reclassification in this petition are the class III metal/metal, semi-constrained total hip prostheses device configurations. It should be noted that metal/polymer, semi-constrained total hip prostheses, which are class II devices, utilize the same femoral prostheses components as do the class III metal/metal hip prostheses.

B. Specific Intended Use

The metal/metal total hip prosthesis is intended for the replacement of the severely painful and/or disabled hip joint resulting from inflammatory arthritis, noninflammatory degenerative joint disease, acute traumatic fracture of the femoral head or neck, traumatic arthritis, diastrophic variant and failed previous surgery including: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or previous total hip replacement.