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## MAYO ® Hip Prosthesis Summary of Safety and Effectiveness

- Submitted By:

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- Device Trade Name

MAYO ® Hip Prosthesis

- Device Classification Name

Hip joint metal/polymer/metal semi-constrained porous uncemented prosthesis

- Predicate Devices

Zimmer ® Anatomic Hip System  
HG MultiLock™ Hip Prosthesis  
BIAS™ Total Hip System

- Device Description

The MAYO Hip Prosthesis is a short-stemmed, press-fit modular femoral component developed by Bernard F. Morrey, M.D., of the Mayo Clinic and is intended to be implanted into the human femur to replace a hip joint. The MAYO Hip incorporates several technological features of the Zimmer Anatomic Hip Prosthesis (and other predicate devices) such as the Morse-type tapered neck and fiber metal pads for bone ingrowth, and is made from the same materials (titanium alloy and commercially pure titanium) as the predicate devices. The femoral stem is collarless, has a dual taper (double wedge) body, and has a short distal stem (tail). The femoral stem is available in four sizes each of which can be utilized in the left or right hip.

The modular femoral stem is designed to mate with a femoral head through a Morse-type taper. The femoral head in turn articulates upon the UHMWPE liner of an acetabular component. The MAYO Hip Prosthesis meets the criteria of the generic device described in 21 CFR 888.3358.

The MAYO Hip supports a conservative approach to total hip arthroplasty by allowing for minimal femoral neck resection, minimal bone preparation, minimal stress shielding, absence of intramedullary fixation, reduction in blood loss, and potential for ease of revision.

The short distal portion of the stem is used to assist in proper placement of the stem and provides for rotary fixation. Immediate fixation is

achieved through three-point (anteroposterior and lateral planes) fixation in the metaphyseal bone of the proximal femur. The stem does not rely upon intramedullary fixation, therefore the source of thigh pain is eliminated. Surgery time is reduced because the femoral medullary canal is not reamed or violated. This results in statistically significant less blood loss than that of a conventional, uncemented primary total hip arthroplasty. Additionally, reduction in the amount of metal (due to the short distal stem and double wedge shape) results in less exposure of a foreign body to the intramedullary canal. The conservative femoral neck resection, which preserves bone stock, will facilitate subsequent procedures should a revision of the hip be required.

- Intended use:

The *MAYO* Hip is used in total hip arthroplasty, a surgical procedure restricted to patients with substantial pain or marked functional disabilities in which conservative treatment has not provided acceptable relief and who are not candidates for other less aggressive forms of surgery. This hip is indicated for noncemented use in skeletally mature individuals. Diagnostic indications include severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, slipped capital femoral epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

- Comparison to Predicate Device

The *MAYO* Hip Prosthesis is substantially equivalent to the hip prostheses listed above as predicate devices. Each is designed as a femoral component that is intended to be implanted into the human femur to replace a hip joint. Each femoral component is manufactured from Titanium Alloy and commercially pure titanium fiber pads which are metallurgically bonded to the proximal body of the stem. All are designed to be used without bone cement. Primary fixation is achieved by press fit. The predicate devices rely upon intramedullary fixation through the presence of a long distal stem while the *MAYO* Hip utilizes a shorter, more conservative, wedge shaped stem to achieve immediate three-point proximal femoral fixation. Secondary fixation is achieved through biological ingrowth into the fiber metal pads. Each femoral component uses a socket and Morse-type taper joint for attaching the femoral head to the stem.

- Clinical and Nonclinical Data

Performance data are available and include Finite Element Analysis (FEA), fatigue testing, characterization of the porous coating, information that addresses the potential for galvanic corrosion, and eight years of clinical research that indicates a satisfactory clinical outcome. Clinical data also reveal a statistically significant reduction in blood loss during surgery and a statistically significant reduction in pain as compared to the *BIAS* Hip prostheses. These performance data validate the claim of substantial equivalence and provide evidence of safety and effectiveness.