

# Summary of Safety & Effectiveness Data for the ULTIMA\* Unipolar Head and Adapter Sleeves

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R 965156

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1. **Contact Person**

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2. **Device Name**

**Proprietary Name:** ULTIMA\* Unipolar Head and Adapter Sleeves  
**Common Name:** Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis  
**Classification Name:** Prosthesis, Hip  
**Regulatory Class:** Class II by 21 CFR § 888.3360  
**Product Code:** 87 JDG  
**Owner/ Operator #** 9001269

3. **Device Classification**

Classification for ULTIMA\* Unipolar Head and Adapter Sleeves has been placed in Class II by 21 CFR § 888.3360

4. **Statement of Substantial Equivalence**

The safety and effectiveness of the ULTIMA\* Unipolar Head and Adapter Sleeves is substantially equivalent in terms of function to the Johnson & Johnson ULTIMA\* Unipolar Modular Head and the Howmedica Unitrax Unipolar System. Furthermore, analysis results demonstrate that the ULTIMA\* Unipolar Head and Adapter Sleeves meets the set criteria for the establishment of "substantial equivalence".

5. **Indications for Use**

The ULTIMA\* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
  - the major pathology affects the femoral head,
  - the acetabular cavity is normal and not deformed or weakened,
  - acetabular replacement is not required or desirable.

## 6. Physical Description

The ULTIMA\* Unipolar Head is provided in a size range of 38mm to 63mm (outer diameter), in 1mm increments. Sizes from 44mm through 63mm are manufactured as a two-piece assembly. The two pieces are made of cast cobalt-chromium-molybdenum alloy conforming to ASTM F75. Both pieces are treated with hot isostatic pressing and solution annealing. The two cast pieces are machined and then joined permanently by electron beam welding to form a hollow unipolar head. Sizes from 38mm through 43mm are cast from cobalt-chromium-molybdenum alloy as a solid head, and are isostatic pressed and solution annealed before machining. Both of these size ranges are finish machined to the outer diameter size. The outer diameter is highly polished for articulation with the implant recipient's natural acetabulum.

The ULTIMA\* Unipolar Head has a tapered bore which can receive a variety of Adapter Sleeves. The adapter sleeves can be tapered on the outside to mate with the unipolar head, and tapered on the inside to mate with the appropriate femoral stem trunnion. The adapter sleeves are available in a 10/12 taper, in size increments for -3mm, +0mm, +5mm, and +10mm neck lengths; in a 11/13 taper, in size increments for +0mm, +6mm, and +12mm neck lengths; and in a 12/14 taper, in size increments for +0mm, +3.5mm, and +7mm neck lengths. The adapter sleeves are machined from cobalt-chromium-molybdenum alloy in wrought bar form conforming ASTM F799.

**Table 1. Similarities and Differences Matrix**

|   | <b>ULTIMA* Unipolar Head and Adapter Sleeves</b>   | <b>ULTIMA* Unipolar Modular Head</b> | <b>Howmedica Unitrax Unipolar System</b> |
|---|--|--------------------------------------|--|
|   | <b>Subject 12365</b>   | <b>K902365</b>                       | <b>K902365</b>                           |
| <b>DESIGN</b>   |  |                                      |  |
| Range of sizes  | 38mm-63mm<br>(1mm increments)  | 38mm-65mm<br>(1mm increments)        | 38mm-63mm<br>(1mm increments)            |
| Adapter sleeve for increased neck length              | Yes  | No                                   | Yes                                      |
| Number neck length sizes                              | <i>10/12 taper:</i> -3mm, +0mm, +5mm, +10mm<br><i>11/13 taper:</i> +0mm, +6mm, +12mm<br><i>12/14 taper:</i> +0mm, +3.5mm, +7mm | +0mm, +5mm                           | -4mm, +0mm, +5mm, +10mm                  |
| Morse-taper locking mechanism to modular femoral stem | Yes  | Yes                                  | Yes                                      |
| <b>INTENDED USE</b>                                   |  |                                      |  |
| Partial hip replacement                               | Yes  | Yes                                  | Yes                                      |
| <b>MATERIALS</b>                                      |  |                                      |  |
| Manufactured from Co-Cr-Mo                            | Yes  | Yes                                  | Yes                                      |