UCP Stem *510(k) Summary*

510(k) Summary of Safety and Effectiveness

Submitter Information

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Name of Device

Trade Name	**UCP Stem**
Common Name	Hip Stem

Regulation Name and Number	The device classification for **UCP Stem** is: 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. This falls under the Orthopedic Panel.
Device Class	Class II
Classification	Orthopedics
Product Code	LZO, JDI, LWJ, KWY
Predicate Device	1. "DePuy" DePuy C-Stem AMT (K082239) 2. "Zimmer" CPT® 12/14 Hip Prostheses (K030265)

Device Description:

UCP (United Cement Polished) stem is a triple tapered, polished, collarless stem. It is available for three series: Standards offset, High offset and Long stem to accommodate

various surgical requirements. UCP Stem is intended to be fixed only with the use of PMMA bone cement and should be used with centralizer and cement restrictor. UCP stem, centralizer and cement restrictor are made of Co-Cr-Mo alloy (ASTM F799-11), PMMA and UHMWPE (ASTM F648-14/ISO5834), respectively. UCP Stem is intended to use for primary or revision hip arthroplasty. For total hip arthroplasty, UCP Stem can be used with UNITED acetabular liner, cup and femoral head. For bipolar hip replacement, UCP Stem can be used with UNITED bipolar prosthesis.

Indications for Use:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.
4. Revision procedures where other treatments or devices have failed.
5. Patients suffering from disability due to previous fusion.
6. Patients with acute femoral neck fractures.

This device is a single use implant and intended for cemented use only.

Comparison to Predicate Device:

From view of the material, design rationale, intended use and sterilization method, UCP Stem is substantial equivalent to the predicate devices. The difference between the subject and the predicate devices is size distribution. However, the stem length of UCP Stem is within the size range of the predicate devices. The difference of size distribution does not affect the intended use of the device or alter the fundamental scientific technology of the device. As a result, UCP Stem is substantially equivalent to the predicate devices.

Performance Data:

- **Non-clinical Performance**

Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device, and the test results comply with the recommendations according to the FDA guidance "Guidance for Industry and FDA Staff: Non-clinical Information for Femoral Stem Protheses".

The following mechanical tests of the UCP Stem were performed:

a. Stem Fatigue Test
b. Neck Fatigue Test
c. Range of Motion
d. Mechanical Testing for Ceramic Femoral Head while Collocating with UCP Stem

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.