510(k) Summary of Safety and Effectiveness

Submitter Information

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Name of Device

Trade Name	Locking Cage, Full XPE Cup
Common Name	Acetabular component

Regulation Name and Number	The device classification for **Locking Cage, Full XPE Cup** are "prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented" and "prosthesis, hip, semi-constrained, metal/polymer, cemented" which are contained in the Code of Federal Regulation, under **21CFR 888.3353 and 21 CFR 888.3350**, respectively. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	LZO, JDI
Predicate Device	1. "Stryker Howmedica Osteonics" GAP-II Restoration Acetabular Shells (K980774) 2. "Smith & Nephew" Cemented all polyethylene Acetabular component (K991026) 3. "United" U-Motion II Acetabular Component (K122185)

4. "Howmedica" Trident® Crossfire® Polyethylene Liners (K021911)

Device Description:

"United" Locking Cage

The "United" Locking Cage is designed to achieve stable and lasting fixation of the severely deficient acetabulum. The "United" Locking Cage includes locking cage and several accessory components including: ischial flange, hook, cancellous locking screw and auto break-off locking nut. They are all manufactured from Ti6Al4V which confirms to ASTM F136-13.

"United" Full XPE Cup

The "United" Full XPE Cup is designed for cemented use and assembled with a PMMA Spacer and an X-ray marking wire. The Full XPE Cup is manufactured from highly cross-linked UHMWPE which conforms to ASTM F2565-06. The UHMWPE raw material is in accordance with ASTM F648-14 and ISO 5834-1:2005. The PMMA Spacer and X-ray marking wire are made of PMMA (Medical Grade) and Co-20Cr-15W-10Ni alloy (ASTM F90-14), respectively. The X-ray marking wire is designed for X-ray image identification purpose. The "United" Full XPE Cup is available in a range of sizes to fit varying anatomical requirements.

The "United" Locking Cage can be used with correspondent sizes of "United" Full XPE Cup with bone cement. The "United" Full XPE Cup is also compatible with "United" Metal Femoral Head (K994078, K022520, K111546 and K122504) and "United" Ceramic Femoral Head (K103497) in correspondent sizes. The "United" Femoral Heads can be used with various types of "United" hip stems (K003237, K062978, K111546, K123550, K132207, K151316 and K152530).

Indications for Use:

For Locking Cage

1. Revision of previous unsuccessful acetabular replacement.
2. Class III segmental and/or cavitary acetabular defects which make it difficult to achieve satisfactory results while using standard total hip replacement acetabular components and procedures.

For Full XPE Cup

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion and femoral neck fractures of the proximal femur with head involvement that is unmanageable using other techniques.

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

Comparison to Predicate Device:

"United" Locking Cage

The "United" Locking Cage is substantially equivalent to "Stryker Howmedica Osteonics" GAP-II Restoration Acetabular Shells (K980774) in indications, design rationale, dimension characteristic and sterilization method.

"United" Full XPE Cup

The Full XPE Cup is substantially equivalent to "Smith & Nephew" REFLECTION cross-linked UHMWPE Acetabular Components (K991026) in indications, material, design rationale, dimension characteristic and sterilization method.

Performance Data:

- **Non-clinical Performance**

  Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device:

  a. Structural compression stiffness of locking cage
  b. ROM for Full XPE Cup
  c. Bending fatigue testing of flanges
  d. Locking strength of locking cage and cemented cup
  e. Endurance testing
  f. Bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

  Performance data demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.