September 20, 2018

MicroPort Orthopedics Inc. (MPO)
% Usman Rashid
Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K173898
Trade/Device Name: MicroPort Orthopedics Total Hip Systems MR Labeling
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, MAY, LPH, MBL, LWJ, KWY, KXA
Dated: August 2, 2018
Received: August 13, 2018

Dear Usman Rashid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173898

Device Name
See indications for use section.

Indications for Use *(Describe)*

CANCELLOUS BONE SCREW
This cancellous bone screw is indicated for use where screw purchase with cancellous bone is required.

PERFECTA II TOTAL HIP SYSTEM
The Perfecta II Hip System is intended for cemented application only. The prosthesis system will be used in indications which are the same as indications for other cemented total hip designs such as the Zimmer Harris/Galante, the Biomet Bimetric, the Harris Precoat and the Howmedica Precision Hip System. Some indications include replacement of the femoral head and acetabular portions of the hip joint due to degenerative bone disease, trauma or complications from failed prostheses.

CERAMIC FEMORAL HEAD
The McCutchen Femoral Hip Prothesis is indicated for relief of pain and restoration of hip function in skeletally mature patients with: bicompartmental joint disease secondary to osteoarthritis, rheumatoid arthritis or traumatic arthritis, avascular necrosis of the femoral head, painful hip dyplasia, acute fracture of the femoral neck, protrusio acetabuli, ankylosis, revision procedures for which an adequate fit may be achieved by the operating surgeon at the time of surgery. This hip stem prosthesis can be used with all short, medium, and long 28 and 32mm Ceramic Femoral Heads.

ORTHOMET ACETABULAR CUP SYSTEM
The intended use for the Orthomet Acetabular Cup System is identical to that of the acetabular cups of the Orthomet PERFECTA Total Hip System. The Orthomet Acetabular Cup is intended for cemented application only. Indications for the Orthomet Acetabular Cup will remain the same as indications for the original acetabular components of the PERFECTA Total Hip system and other acetabular cup systems currently available in commercial distribution, such as the Depuy Solution Acetabular Cup, Intermedics APR Acetabular Cup, Joint Medical Products S-ROM Acetabular Cup, Smith & Nephew Richards opti-Fix Acetabular Cup, and smith & Nephew Richards Reflection Acetabular Cup. Some indications include replacement of the femoral head and acetabular portions of the hip joint due to degenerative bone disease, trauma, or complications from failed prostheses.

SLT FEMORAL HEAD
This femoral head can only be used with stems labeled for use with this product, and the stem labeling should be consulted to determine its compatibility with this product. The SLT Femoral Head may be used with appropriately sized polyethylene-lined acetabular cups or bipolar endoprostheses.

ORTHOMET RESURFACING FEMORAL COMPONENT
The Orthomet Resurfacing Femoral Component (from this point forward referred to as the Resurfacing Femoral Component) is intended for single use in a cemented application only. The Resurfacing Femoral Component will be used in indications which are the same as indications for other commercially available femoral resurfacing components such as the Endotec Integrated Resurfacing Hip, DePuy Indiana Conservative Hip, DePuy T.A.R.A. Hemi Articular Hip Replacement, and Zimmer THARIES Surface Replacement System. Some indications include resurfacing of the femoral head portion of the hip joint due to avascular necrosis, degenerative bone disease, trauma, or complications from failed prostheses.

SLT 28MM XXL FEMORAL HEAD

The SLT 28mm XXL Femoral Head is indicated in total hip arthroplasty for reductionor relief of pain and/or improved hip function in skeletally mature patients with thefollowing conditions:

1) Non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;

2) Inflammatory degenerative joint disease such as rheumatoid arthritis;

3) Correction of functional deformity;

4) Revision procedures where other treatments or devices have failed; and

5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximalfemur with head involvement that are unmanageable using other techniques.

LINEAGE ACETABULAR SYSTEM

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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) correction of functional deformity;

4) revision procedures where other treatments or devices have failed; and,

5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

PRO-FEMUR R

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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) correction of functional deformity;

4) revision procedures where other treatments or devices have failed; and,

5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

PERFECTA AND EXTEND

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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) correction of functional deformity;

4) revision procedures where other treatments or devices have failed; and,

5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

PRO-FEMUR

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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) correction of functional deformity;

4) revision procedures where other treatments or devices have failed; and,

5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

STEM HIP REPLACEMENT SYSTEM, MODEL PHA002XX
Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Treatment of fractures that are unmanageable using other techniques.

PROCOTYL-E ACETABULAR SYSTEM
The PROCOTYL-E Acetabular System is indicated for use in total hip arthroplasty forreduction or relief of pain and/or improved hip function in skeletally mature patients withthe following conditions:
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of fractures that are unmanageable using other techniques.
The PROCOTYL-E Acetabular System consists of single use components that areintended to accommodate for bone loss. This system is to be used in conjunction with associated WMT polyethylene and metal Acetabular liners articulating with associated WMT metal and ceramic femoral heads as part of an uncemented total hip arthroplasty.

PROFEMUR RENAISSANCE HIP STEM
The PROFEMUR® RENAISSANCE™ Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

LINEAGE A-CLASS POLY LINER
Indications For Use:The LINEAGE® A-CLASS™ Poly Liner is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

PROFEMUR XTR HIP STEM
The PROFEMUR® XTR Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

PROFEMUR TL HIP STEM
ThePROFEMUR® TL Hip Stem is indicated for use in total hip arthroplasty for reductionor relief of pain and/or improved hip function in skeletally mature patients with thefollowing conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosls,arlkylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER

The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with thefollowing conditions:
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosls, arlkylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

GLADIATOR BIPOLAR SYSTEM

The GLADIATOR® Bipolar System is indicated for the following conditions:
1. pathological fractures of the femoral neck.
2. non-union of femoral neck fractures.
3. aseptic necrosis of the femoral head and neck.
4. primary pathology in the young involving the femoral head but wuth non-deformed acetabulum

CONSERVE FEMORAL RESURFACING COMPONENT

The CONSERVE® Femoral Resurfacing Component is indicated for use in hemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non- inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis,protrusion acetabuli, and painful hip dysplasia.The CONSERVE® Femoral Resurfacing Component is indicated for cemented use only.

DYNASTY ACETABULAR SYSTEM

The DYNASTY™ Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.The DYNASTY™ Acetabular Shell is for both cemented and uncemented use.

DYNASTY CERAMIC FEMORAL HEAD

The DYNASTY™ Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.
The DYNASTY™ Acetabular Shell is for both cemented and uncemented use.

CONSERVE PRESSFIT FEMORAL COMPONENT

The CONSERVE® Pressfit Femoral Resurfacing Component is indicated for use inhemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.
CONSERVE® Pressfit Femoral Resurfacing Component is intended for non-cemented use.

DYNASTY POROUS ACETABULAR SHELL, POLYETHYLENE ACETABULAR LINER, METAL ACETABULAR LINER

The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The size 50 and 54mm ceramic femoral heads are only intended for patients with giganticism or malunion of the acetabulum, and/or revision.

The DYNASTY® Acetabular Shell is for both cemented and uncemented use and is a single use device.

PROFEMUR HIP SYSTEM MODULAR NECKS

The PROFEMUR® Hip System Modular Necks are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

Modular necks can be used during either cemented or uncemented femoral and acetabular arthroplasty.

GLADIATOR PLASMA CLASSIC HIP STEM

The GLADIATOR® Plasma Classic Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The GLADIATOR® Plasma Classic Hip Stem are intended for use during uncemented hip arthroplasty

PROFEMUR(R) E CEMENTLESS HIP STEM

The PROFEMUR® E Cementless Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® E Cementless Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM

The PROFEMUR® Z Titanium Plasma Sprayed Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Z Titanium Plasma Sprayed Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

GLADIATOR HIP STEM
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.The Gladiator cpTi Plasma Sprayed hip stem is intended for cementless hip arthroplasty.
The Gladiator Cemented hip stem is intended for cemented hip arthroplasty.

PRESERVE HIP STEM
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.The Preserve hip stem is intended for cementless hip arthroplasty.

PROFEMUR GLADIATOR HA HIP STEM
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.
The PROFEMUR® Gladiator HA Hip Stem is intended for cementless hip arthroplasty.

PROFEMUR Z REVISION HIP STEM
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.
The PROFEMUR® Z Revision Hip Stem is intended for cementless hip arthroplasty.

PROFEMUR Z CLASSIC STEMS
The PROFEMUR® Z Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.
The PROFEMUR® Z Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

PROFEMUR TL CLASSIC HIP STEM
The PROFEMUR® TL Classic Stems are indicated for use in total hip arthroplasty forreduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.
The PROFEMUR® TL Classic Stems are single use components, intended for use inconjunction with associated ceramic

or metal femoral heads as part of uncemented total hip arthroplasty.

PROFEMUR XM DISTAL CENTRALIZER

The PMMA Distal Centralizers are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PMMA Distal Centralizers are single use components, intended for use as part of a cemented total hip arthroplasty.

DYNASTY ACETABULAR SYSTEM WITH CERAMIC

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

PROFEMUR RENAISSANCE CLASSIC HIP STEM

The PROFEMUR® RENAISSANCE® Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® RENAISSANCE® Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

DYNASTY SHELL, DYNASTY A-CLASS CROSSLINKED POLY LINER, BIOLOX DELTA FEMORAL HEAD

The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failedShells with BIOFOAM metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

PROFEMUR TL CLASSIC LONG NECK HIP STEMS

The PROFEMUR® TL Classic Long Neck Hip Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® TL Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

PROFEMUR RENAISSANCE CLASSIC LONG NECK HIP STEMS

The PROFEMUR® RENAISSANCE® Classic Long Neck Hip Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® RENAISSANCE® Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

PROCOTYL L-O ACETABULAR SYSTEM

The PROCOTYL® L-O Acetabular System is intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROCOTYL® L-O Acetabular System utilizes single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.

PROFEMUR Preserve Size 1-3 Hip Stems

The PROFEMUR® Preserve Sizes 1-3 Hip Stems are intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Preserve Sizes 1-3 Hip Stems are single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.

PROFEMUR Preserve Classic Stem

The PROFEMUR® Preserve Classic Stems are intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Preserve Classic Stems are single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.

PROCOTYL PRIME ACETABULAR CUP SYSTEM

The PROCOTYL® PRIME Acetabular Cup System is intended for use in total hip arthroplasty for reduction or relief ofpain and/or improved hip function in skeletally mature patients with the following conditions:

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) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

PROCOTYL® PRIME E-CLASS™ XLPE Liner

The PROCOTYL® PRIME E-CLASS™ XLPE Liner is intended for use in total hiparthroplasty for reduction or relief of pain and/or improved hip function in skeletallymature patients. This device is indicated for the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, ankyloses, protrusion acetabuli, and painful hip dysplasia;

2) inflammatory degenerative joint disease such as rheumatoid arthritis;

3) correction of functional deformity; and,

4) revision procedures where other treatments or devices have failed.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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MicroPort Orthopedics Inc.

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the MicroPort Orthopedics' (MPO) hip systems in an MRI environment.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd Arlington, TN 38002 Phone: (866) 872-0211 Fax: (855) 446-2247
Date:	September 19th, 2018
Contact Person:	Usman Rashid *Regulatory Affairs Specialist II*
Proprietary Name of Modified Device:	MicroPort Orthopedics Inc. Hip Systems MR Labeling
Common Name:	MPO Total Hip System - Femoral Hip Stem, Femoral Head, Acetabular Shell, Acetabular Liner
Classification Name and Reference:	888.3353 LZO Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis Class II 888.3350 JDI Hip joint metal/polymer semi-constrained cemented prosthesis Class II 888.3353 MAY Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II

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Classification Name and Reference (cont):

888.3358 LPH
Hip joint metal/polymer/metal semi-Constrained porous-coated uncemented prosthesis
Class II

888.3358 MBL
Hip joint metal/polymer/metal semi-Constrained poruous-coated uncemented prosthesis
Class II

888.3360 LWJ
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Class II

888.3390 KWY
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Class II

888.3400 KXA
Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Class II

Subject Product Code and Panel Code:

Orthopedics/87/LZO/JDI/MAY/LPH/MBL/LWJ/KWY/KXA

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Predicate Devices:

Table 1: Predicate Table with Submission Numbers and Descriptions

Submission Number	Description
K864626	CANCELLOUS BONE SCREW
K883618	PERFECTA II TOTAL HIP SYSTEM
K893685	CERAMIC FEMORAL HEAD
K931333	ORTHOMET ACETABULAR CUP SYSTEM
K932222	SLT FEMORAL HEAD
K944752	ORTHOMET RESURFACING FEMORAL COMPONENT
K953025	SLT 28MM XXL FEMORAL HEAD
K002149	LINEAGE ACETABULAR SYSTEM
K003016	PRO-FEMUR R
K004032	PERFECTA AND EXTEND
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM, MODEL PHA002XX
K043073	PROCOTYL-E ACETABULAR SYSTEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052026	LINEAGE A-CLASS POLY LINER
K052915	PROFEMUR XTR HIP STEM
K060358	PROFEMUR TL HIP STEM
K061547	DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER
K062693	GLADIATOR BIPOLAR SYSTEM
K062960	CONSERVE FEMORAL RESURFACING COMPONENT
K070785	DYNASTY ACETABULAR SYSTEM
K072656	DYNASTY CERAMIC FEMORAL HEAD
K082673	CONSERVE PRESSFIT FEMORAL COMPONENT
K082924	DYNASTY POROUS ACETABULAR SHELL, POLYETHYLENE ACETABULAR LINER, METAL ACETABULAR LINER
K091423	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEMS

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Table 1: Predicate Table with Submission Numbers and Descriptions (cont.)

Submission Number	Description
K123688	PROFEMUR TL CLASSIC HIP STEM
K130167	PROFEMUR XM DISTAL CENTRALIZER
K130376	DYNASTY ACETABULAR SYSTEM WITH CERAMIC
K130984	PROFEMUR RENAISSANCE CLASSIC HIP STEM
K140043	DYNASTY SHELL, DYNASTY A-CLASS CROSSLINKED POLY LINER, BIOLOX DELTA FEMORAL HEAD
K140676	PROFEMUR TL CLASSIC LONG NECK HIP STEMS
K141235	PROFEMUR RENAISSANCE CLASSIC LONG NECK HIP STEMS
K142119	PROCOTYL L-O ACETABULAR SYSTEM
K150133	PROFEMUR Preserve Size 1-3 Hip Stems
K150302	PROFEMUR Preserve Classic Stem
K170444	PROCOTYL PRIME ACETABULAR CUP SYSTEM
K171181	PROCOTYL® PRIME E-CLASS™ XLPE Liner

Device Description

The only changes to the subject hip systems are updates to the labeling of the devices. Specifically, the package inserts and package labels are being updated to include MR Conditional language and symbols. The subjects are identical to the predicates in all aspects except for the labeling updates. Testing is provided in this Traditional 510(k) that establishes the safety and compatibility of the passive implants in a magnetic resonance (MR) environment.

The subject devices are a variety of hip joint replacement prostheses. The components for these systems include an acetabular shell, acetabular liner, fixation screws, femoral head, femoral stem, modular neck, proximal body, centralizers, bone plugs, and neck sleeves. These components can be utilized in a variety of configurations to assemble the final construct.

The femoral and acetabular components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, alumina ceramic, Alumina Matrix Composite ceramic (Biolox Delta), polymethylmethacrylate (PMMA), and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards.

Intended Use

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

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. correction of functional deformity; and,

4. revision procedures where other treatments or devices have failed

The MicroPort total hip systems devices are single use only devices.

The indications for use for the predicate systems are included in Table 2 below:

Table 2: Indications for Use

510(k) Number	Indication for Use
K864626	This cancellous bone screw is indicated for use where screw purchase with cancellous bone is required.
K883618	The Perfecta II Hip System is intended for cemented application only. The prosthesis system will be used in indications which are the same as indications for other cemented total hip designs such as the Zimmer Harris/Galante, the Biomet Bimetric, the Harris Precoat and the Howmedica Precision Hip System. Some indications include replacement of the femoral head and acetabular portions of the hip joint due to degenerative bone disease, trauma or complications from failed prostheses.
K893685	The McCutchen Femoral Hip Prothesis is indicated for relief of pain and restoration of hip function in skeletally mature patients with: bicompartmental joint disease secondary to osteoarthritis, rheumatoid arthritis or traumatic arthritis, avascular necrosis of the femoral head, painful hip dyplasia, acute fracture of the femoral neck, protrusio acetabuli, ankylosis, revision procedures for which an adequate fit may be achieved by the operating surgeon at the time of surgery. This hip stem prosthesis can be used with all short, medium, and long 28 and 32mm Ceramic Femoral Heads.
K931333	The intended use for the Orthomet Acetabular Cup System is identical to that of the acetabular cups of the Orthomet PERFECTA Total Hip System. The Orthomet Acetabular Cup is intended for cemented application only. Indications for the Orthomet Acetabular Cup will remain the same as indications for the original acetabular components of the PERFECTA Total Hip system and other acetabular cup systems currently available in commercial distribution, such as the Depuy Solution Acetabular Cup, Intermedics APR Acetabular Cup, Joint Medical Products S-ROM Acetabular Cup, Smith & Nephew Richards opti-Fix Acetabular Cup, and smith & Nephew Richards Reflection Acetabular Cup. Some indications include replacement of the femoral head and acetabular portions of the hip joint due to degenerative bone disease, trauma, or complications from failed prostheses.
K932222	This femoral head can only be used with stems labeled for use with this product, and the stem labeling should be consulted to determine its compatibility with this product. The SLT Femoral Head may be used with appropriately sized polyethylene-lined acetabular cups or bipolar endoprostheses.

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510(k) Number	Indication for Use
K944752	The Orthomet Resurfacing Femoral Component (from this point forward referred to as the Resurfacing Femoral Component) is intended for single use in a cemented application only. The Resurfacing Femoral Component will be used in indications which are the same as indications for other commercially available femoral resurfacing components such as the Endotec Integrated Resurfacing Hip, DePuy Indiana Conservative Hip, DePuy T.A.R.A. Hemi Articular Hip Replacement, and Zimmer THARIES Surface Replacement System. Some indications include resurfacing of the femoral head portion of the hip joint due to avascular necrosis, degenerative bone disease, trauma, or complications from failed prostheses.
K953025	The SLT 28mm XXL Femoral Head is indicated in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) Correction of functional deformity; 4) Revision procedures where other treatments or devices have failed; and 5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
K002149	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; and, 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
K003016	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; and, 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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510(k) Number	Indication for Use
K004032	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; and, 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
K012091	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; and, 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
K021346	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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) Correction of functional deformity; 4) Revision procedures where other treatments or devices have failed; and, 5) Treatment of fractures that are unmanageable using other techniques.
K043073	The PROCOTYL-E Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; 4. revision procedures where other treatments or devices have failed; and, 5. treatment of fractures that are unmanageable using other techniques. The PROCOTYL-E Acetabular System consists of single use components that are intended to accommodate for bone loss. This system is to be used in conjunction with associated WMT polyethylene and metal Acetabular liners articulating with associated WMT metal and ceramic femoral heads as part of an uncemented total hip arthroplasty.

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510(k) Number	Indication for Use
K051995	The PROFEMUR® RENAISSANCE™ Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed
K052026	The LINEAGE® A-CLASS™ Poly Liner is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed
K052915	The PROFEMUR® XTR Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed
K060358	ThePROFEMUR® TL Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed
K061547	The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosls, arlkylosis, protrusio acetabuli, and painful hip dysplasia; 2. inflammatory degenerative joint disease such as rheumatoid arthritis; 3. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed

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510(k) Number	Indication for Use
K062693	The GLADIATOR® Bipolar System is indicated for the following conditions: 1. pathological fractures of the femoral neck 2. non-union of femoral neck fractures 3. aseptic necrosis of the femoral head and neck 4. primary pathology in the young involving the femoral head but wuth non-deformed acetabulum
K062960	The CONSERVE® Femoral Resurfacing Component is indicated for use in hemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non- inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia. The CONSERVE® Femoral Resurfacing Component is indicated for cemented use only.
K070785	The DYNASTY™ Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The DYNASTY™ Acetabular Shell is for both cemented and uncemented use.
K072656	The DYNASTY™ Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The DYNASTY™ Acetabular Shell is for both cemented and uncemented use.
K082673	The CONSERVE® Pressfit Femoral Resurfacing Component is indicated for use in hemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia. CONSERVE® Pressfit Femoral Resurfacing Component is intended for non-cemented use

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510(k) Number	Indication for Use
K082924	The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The size 50 and 54mm ceramic femoral heads are only intended for patients with giganticism or malunion of the acetabulum, and/or revision. The DYNASTY® Acetabular Shell is for both cemented and uncemented use and is a single use device.
K091423	The PROFEMUR® Hip System Modular Necks are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed Modular necks can be used during either cemented or uncemented femoral and acetabular arthroplasty.
K110399	The GLADIATOR® Plasma Classic Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed The GLADIATOR® Plasma Classic Hip Stem are intended for use during uncemented hip arthroplasty
K111698	The PROFEMUR® E Cementless Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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;

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	3. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed The PROFEMUR® E Cementless Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.
K111699	The PROFEMUR® Z Titanium Plasma Sprayed Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed The PROFEMUR® Z Titanium Plasma Sprayed Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.
K111910	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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The Gladiator cpTi Plasma Sprayed hip stem is intended for cementless hip arthroplasty. The Gladiator Cemented hip stem is intended for cemented hip arthroplasty.
K112080	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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The Preserve hip stem is intended for cementless hip arthroplasty.
K112150	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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® Gladiator HA Hip Stem is intended for cementless hip arthroplasty.

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510(k) Number	Indication for Use
K121221	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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® Z Revision Hip Stem is intended for cementless hip arthroplasty.
K123434	The PROFEMUR® Z Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® Z Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.
K123688	The PROFEMUR® TL Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® TL Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.
K130167	The PMMA Distal Centralizers are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed The PMMA Distal Centralizers are single use components, intended for use as part of a cemented total hip arthroplasty.
K130376	Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;

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	2. inflammatory degenerative joint disease such as rheumatoid arthritis; 3. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed
K130984	The PROFEMUR® RENAISSANCE® Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® RENAISSANCE® Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.
K140043	The DYNASTY® Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed Shells with BIOFOAM metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.
K140676	The PROFEMUR® TL Classic Long Neck Hip Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® TL Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.
K141235	The PROFEMUR® RENAISSANCE® Classic Long Neck Hip Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and,

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	4. revision procedures where other treatments or devices have failed. The PROFEMUR® RENAISSANCE® Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.
K142119	The PROCOTYL® L-O Acetabular System is intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROCOTYL® L-O Acetabular System utilizes single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.
K150133	The PROFEMUR® Preserve Sizes 1-3 Hip Stems are intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® Preserve Sizes 1-3 Hip Stems are single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.
K150302	The PROFEMUR® Preserve Classic Stems are intedned for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 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. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed. The PROFEMUR® Preserve Classic Stems are single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.
K170444	The PROCOTYL® PRIME Acetabular Cup System is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

510(k) Number	Indication 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) correction of functional deformity; and, 4) revision procedures where other treatments or devices have failed. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty
K171181	The PROCOTYL® PRIME E-CLASS™ XLPE Liner is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients. This device is indicated for the following conditions: 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankyloses, protrusion acetabuli, and painful hip dysplasia; 2) inflammatory degenerative joint disease such as rheumatoid arthritis; 3) correction of functional deformity; and, 4) revision procedures where other treatments or devices have failed. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

Technological Characteristics of the Device

The indications for use of the MPO Hip Systems MR Labeling devices are not changing. The subject devices' materials are not changing. The devices will be unchanged except for updates to the labeling of the devices. Specifically, the package inserts and package labels are being updated to include MR Conditional language and symbols. The subjects are identical to the predicates in all aspects except for the labeling updates.

Nonclinical Testing

Non clinical Testing was conducted to establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment according to the recommendations provided in the guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" issued on December 11, 2014. Testing was also conducted according to the following standards:

ASTM F2052-6, "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment";

ASTM F2119-7 "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants";

ASTM F2503-13 "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment";

ASTM F2182-11a "Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants During Magnetic Resonance Imaging"

The tests determined the effects of the MRI on the implants, and the effects of the implants on the image quality. The tests evaluated the worst case components and constructs for RF Heating, field interactions, and image artifacts. The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labeling.

Clinical Testing
Clinical data was not provided for the subject devices.

Conclusions
All the information provided in this submission adequately supports the substantial equivalence of the labeling change.