April 18, 2024

MicroPort Orthopedics
Sam Robertson
Regulatory Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K240046
Trade/Device Name: Ethylene Oxide Sterilization Supplier Change for MPO Hips
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, LZO, MBL, KWY, HWC, OQG, OQI, KXA, LZN
Dated: March 22, 2024
Received: March 22, 2024

Dear Sam Robertson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
LINEAGE ACETABULAR SYSTEM (indications identical to 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 osteoartlifitis, 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

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
LINEAGE A-CLASS POLY LINER (indications identical to 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

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER (indications identical to K061547)

The DYNASTYTM Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip fiinction in skeletally mature patients with the following conditions:
1. non-inflammatory degenerative joint di:sease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease suclh as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
GLADIATOR BIPOLAR SYSTEM (indications identical to K062693)

The GLADIATORTm 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 with a non-deformed acetabulum.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
Dynasty Acetabular System (indications identical to 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.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
DYNASTY CERAMIC FEMORAL HEAD (indications identical to K072656)

The DYNASTYTM 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 finctional deformity; and,
4. revision procedures where other treatments or devices have failed.

The DYNASTYTM Acetabular Shell is for both cemented and uncemented use.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
GLADIATOR HIP STEM (indications identical to K111910)

The Gladiator Hip Stems are intended for use in uncemented and cemented total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dlysplasia;
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 Cemented hip stem is intended for cemented hip 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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
DYNASTY® Acetabular System with Ceramic (indications identical to K140043)

MicroPort 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-inflamnmatory 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 shells with porous metal bead coating may be used in either cemented or uncemented artbroplasty. 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)

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See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
PROCOTYL L-O ACETABULAR SYSTEM (indications identical to K142119)

The PROCOTYL L-O Acetabular 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:

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 conjuction with associated ceramic femoral heads as part of uncemented total hip 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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
PROCOTYL® PRIME Acetabular Cup System (indications identical to 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:

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

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)

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See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
PROCOTYL® PRIME E-CLASS™ XLPE Liner (indications identical to K171181)

PROCOTYL® PRIME hip system is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use
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.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
BIOLOX® Delta Option and Extra-long Heads (indications identical to K173776)

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 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.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
Prime Acetabular Cup System (indications identical to K180798)

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) 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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
Prime E-CLASS™ XLPE Liner (indications identical to K181598)

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) 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS (indications identical to K200011)

The DYNASTY® Dual Mobility Inserts and Liners, when used with compatible acetabular shells and femoral heads, are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients. In revision arthroplasties, all devices associated with the wear couple must be removed and replaced.

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) correction of functional deformity; and;
4) revision procedures where other treatments or devices have failed;
5) dislocation risks;
6) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement which are unmanageable by other techniques
Dual Mobility Inserts and Liners are single use implants intended 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)

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Indications for Use

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Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
Bipolar Hip System (indications identical to K892398)

The Bipolar Hip System is intended for cemented and cementless applications. Some indications include replacement of the femoral head of the hip joint due to degenerative bone disease, trauma, non-union or avascular necrosis.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
NEXUS FEMORAL HIP PROSTHESIS (indications identical to K911052)

The NEXUS Femoral Hip Prosthesis 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 dysplasia, acute fracture of the femoral neck, protrusio acetabuli, ankylosis, and revision procedures for which an adequate fit may be achieved by the operating surgeon at the time of surgery.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
Cement Restrictor for Proforma & PERFECTA Total Hip Systems (indications identical to K923909)

The Orthomet Cement Restrictor is intended to be used with the PROFORMA and PERFECTA Femoral Stems as part of the PROFORMA and PERFECTA Total Hip Systems. The intended use of the Orthomet PROFORMA and PERFECTA Femoral Stems implanted with the Cement Restrictor will remain the same as indications for femoral stems implanted without the Cement Restrictor. Some indications include replacement of the femoral head of the hip joint due to degenerative bone disease, trauma, non-union, avascular necrosis, or complications from failed prostheses. The Orthomet Cement Restrictor is designed to prevent the bone cement from extruding down the medullary canal, during cemented application, when the femoral stem is inserted or the cement is pressurized.

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)

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510(k) Number *(if known)*
K240046

Device Name
Ethylene Oxide Sterilization Supplier Change for MPO Hips

Indications for Use *(Describe)*
ORTHOMET ACETABULAR CUP SYSTEM (indications identical to 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.

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)

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510(k) #: K240046

510(k) Summary

Prepared on: 2024-04-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MicroPort Orthopedics
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Correspondent Contact	Mr. Sam Robertson
Correspondent Contact Email	sam.robertson@ortho.microport.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ethylene Oxide Sterilization Supplier Change for MPO Hips
Common Name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Regulation Number	888.3358
Product Code	LPH; JDI; LZO; MBL; KWY; HWC; OQG; OQI; KXA; LZN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K002149	LINEAGE ACETABULAR SYSTEM	LPH
K052026	LINEAGE A-CLASS POLY LINER	LPH
K061547	DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY A	LPH
K062693	GLADIATOR BIPOLAR SYSTEM	KWY
K070785	DYNASTY ACETABULAR SYSTEM	LPH
K072656	DYNASTY CERAMIC FEMORAL HEAD	LZO

K111910	GLADIATOR HIP STEM	JDI
K140043	DYNASTY SHELL; DYNASTY A-CLASS CROSSLINKED POLY	LZO
K142119	PROCOTYL L-O ACETABULAR SYSTEM	LPH
K170444	PROCOTYL PRIME Acetabular Cup System	LPH
K171181	PROCOTYL PRIME E-CLASS XLPE Liner	LZO
K180798	Prime Acetabular Cup System	LPH
K181598	Prime E-CLASS XLPE Liner	LZO
K200011	E-CLASS DUAL MOBILITY INSERTS and DYNASTY DUAL MO	LPH
K892398	BIPOLAR HIP SYSTEM	KXA
K911052	NEXUS™ FEMORAL HIP STEM	JDI
K923909	CEMENT RESTRICTOR FOR PROFORMA AND PERFECTA TC	LZN
K931333	ORTHOMET ACETBAULAR CUP SYSTEM	LPH
K173776	BIOLOX Delta Option and Extra-long Heads	LZO

Device Description Summary

21 CFR 807.92(a)(4)

A change in ethylene oxide (EO) sterilization supplier is taking place, affecting MicroPort Orthopedics ceramic, ultra-high molecular weight polyethylene, polymethyl methacrylate, and UHMWPE/metal combinations. The subject devices consist of multiple devices across multiple systems. The subject devices are identical to the predicate devices in all aspects, and the only change is to the sterilization supplier and sterilization parameters. The subject devices include the following affected components:

- Metal shell inserts composed of ultra-high molecular weight polyethylene (UHMWPE) and vitamin E cross-linked polyethylene (VEXLPE)
- Distal cement spacer composed of polymethyl methacrylate (PMMA)
- Femoral heads composed of ceramic
- Acetabular Liners composed of UHMWPE with Ti Bead X-ray markers, UHMWPE GUR 1050, GUR 1020 XLPE, and GUR 1020 VEXLPE
- Acetabular Cups composed of UHMWPE GUR 1050
- Titanium Apical Hole Plug with a polyoxymethylene handle
- Bipolar Heads composed of UHMWPE and cobalt chrome alloy
- Centralizers composed of PMMA

The subject materials conform to the following standards:

- UHMWPE GUR 1050, XLPE GUR 1020, and VEXLPE GUR 1020 conforming to ASTM F648
- UHMWPE blended with Vitamin E conforming to ASTM F2695
- Ceramic conforming to ISO 6474
- Wrought titanium alloy conforming to ASTM F136
- Polyoxymethylene conforming to ASTM D6778
- Cobalt chrome alloy conforming to ASTM F75
- Unalloyed titanium conforming to ASTM F67

The sterilization type and sterility assurance level are not affected by the change and remain identical. The current EO sterilization supplier and the new EO supplier use similar parameters in their EO sterilization cycles, and a comparison of the parameters can be found in the Ethylene Oxide Sterilization Validation Report. The subject sterilization process underwent sterilization validation per standards ISO 11135:2014, ISO/TS 21387, and ISO 10993-7:2008 to demonstrate the new sterilization supplier can sterilize MPO products

to a Sterility Assurance level of 10^-6 or less. The sterilization validation shows that the new subject process is capable of achieving the same sterility performance compared to the predicate process. The subject device pouch and blister packaging underwent validation testing per ISO 11607-1:2019, ISO 11607-2:2019, ASTM F88, ASTM F1886, and ASTM F1829 to demonstrate the sterile barrier is capable of withstanding an increase of pressure rate. Furthermore, biocompatibility assessment of the subject materials determined material properties and device characteristics are unaffected by the subject modification.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Please refer to the Indications for Use forms 3881 for the indications for each included 510(k).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device indications for use are the same as the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The design features and materials of the subject device are substantially equivalent to those of the predicate devices. The indications for use and intended patient populations are identical to the predicate devices. The fundamental scientific technology of the subject device has not changed relative to the predicate device. The only changes are to ethylene oxide sterilization parameters, and the changes were validated and determined to not have an effect to the safety or effectiveness of the devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No bench testing, animal testing, or clinical testing was done to support this submission. Sterilization validation testing per ISO 11135:2014, ISO/TS 21387, and ISO 10993-7:2008 was performed to support the subject modification.

N/A. No clinical data were necessary to support the subject change.

Validations concluded that the ethylene oxide sterilization change in supplier and parameter does not affect the design, safety, or effectiveness of the subject devices. The subject devices are as safe, as effective, and perform the same as predicate devices.