October 1, 2021

Microport Orthopedics, Inc.
Matthew Paul
Sr. Regulatory Affairs Project Manager
5677 Airline Road
Arlington, Tennessee 38002

Re: K200011
Trade/Device Name: E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS
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, KWY, LZO, OQG
Dated: September 2, 2021
Received: September 3, 2021

Dear Matthew Paul:

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/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 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 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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200011

Device Name
E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS

Indications for Use *(Describe)*

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitted By:	MicroPort Orthopedics Inc. 5677 Airline Road Arlington, TN 38002 Telephone Number: (901) 290-5175
Date Prepared:	October 1, 2021
Contact Person:	Matthew Paul Sr. Regulatory Affairs Project Manager Telephone number: (901) 867-4350 Email: matt.paul@ortho.microport.com
Name of Device:	E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS
Common Name:	Dual Mobility Inserts and Dual Mobility Liners
Device Classification Name	21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
And Reference:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Device Class:	Class II
Panel Code:	Orthopedics/87
Product Code:	LPH, KWY, LZO, OQG
Predicate Device:	ZIMMER BIOMET G7® DUAL MOBILITY SYSTEM (K150522)
Additional Predicate:	ZIMMER BIOMET G7® DUAL MOBILITY SYSTEM (K161190)
Reference Devices:	MEDACTA VERSAFITCUP® (K083116) ORTHOMET BIPOLAR HIP SYSTEM (K892398) PROCOTYL® PRIME® E-CLASS® XLPE LINERS (K171181) DYNASTY® COCR ACETABULAR LINERS (K061844)

Device Description:

The Dual Mobility (DM) Inserts and Liners are designed for use with compatible DYNASTY® acetabular shells, MicroPort Orthopedics non-skirted femoral heads and PROFEMUR® femoral stems, to create a system with two articulating interfaces in the acetabular joint space of the hip.

The E-CLASS® DUAL MOBILITY INSERTS are manufactured from Vitamin E cross linked polyethylene conforming to ASTM F2695 and are available with an inner diameter of 28 mm and outer diameters from 38 mm to 56 mm in 2 mm increments. The E-Class® DM Inserts are compatible with and provide a primary articulating surface for all 28 mm, non-skirted femoral heads.

DM CoCr Liners are manufactured from cobalt chrome (CoCr) alloy conforming to ASTM F1537 (Type 1) and are available with inner diameters from 38 mm to 56 mm in 2 mm increments. The DM CoCr Liners are designed to mate with all DYNASTY® acetabular shells via a taper locking mechanism and provide the secondary articulating surface for the E-Class® DM Inserts.

Intended Use Statement:

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.

Comparison of Technological Characteristics with the Predicate device:

Device comparison described in this premarket notification demonstrates that the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS are substantially equivalent to the identified predicate ZIMMER BIOMET G7® DUAL MOBILITY SYSTEM (K150522) cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have similar technological characteristics to their predicate and reference devices in areas including design, intended use, material composition, operational principles and function.

Discussion of the Non-clinical Testing/Performance Data:

Mechanical Testing:

MicroPort has evaluated the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS and data demonstrates substantial equivalence to the identified predicate ZIMMER BIOMET G7® DUAL MOBILITY SYSTEM (K150522).

The testing and engineering analyses performed for the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS included:

1. Range of Motion (ROM) Analysis utilizing EN ISO 21535 (2009)
2. Impingement Testing utilizing ASTM F2582-14, ASTM F1820-13, ISO 14242-1 (2014), ISO 14242-2 (2016),
3. Static Disassociation Testing of a femoral head from a dual mobility insert, utilizing ASTM F1820-13
4. High Angle Edge Loading (Fatigue Testing) utilizing ASTM F2003-02(2015), ISO 7206-6:2013
5. Fretting and Corrosion Observational Assessment utilizing ASTM F2003-02(2015), ISO 7206-6:2013
6. Wear Testing and Engineering Analysis utilizing ISO 14242-1 (2014), ISO 14242-2 (2016), ISO 14242-3 (2009)/Amd 1 (2019)
7. Push-out, Lever-out, Torque-out (PO/LO/TO) Testing of a dual mobility liner from a shell, utilizing ASTM F1820-13
8. Magnetic Resonance Imaging (MRI) Safety Evaluation utilizing ASTM F2052-6, ASTM F2119-7, ASTM F2182-11a
9. Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Rationale utilizing ASTM F2003-02(2015), ASTM F2102-13, ASTM F2183-02, ASTM F2214-02, ASTM F2565-13,

ASTM F2625-10, ASTM F2695-12, ASTM F2381-10, ISO 5834-2 (2011), ISO 5834-3 (2005), ISO 5834-4 (2005), ISO 5834-5 (2005), ISO 11542-2 (1998), ISO 527-3 (1995)

The data demonstrate that the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS are substantially equivalent to the legally marketed predicate, ZIMMER BIOMET G7® DUAL MOBILITY SYSTEM (K150522). Having met all acceptance criteria for mechanical testing performed on worst case constructs, the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS do not introduce new or modified risks for safety and effectiveness compared to the predicate or other reference MicroPort Hip Systems and acetabular components which utilize comparable test methods and acceptance criteria.

Conclusion:

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, principle of operations and results of the mechanical testing, the subject E-CLASS® DUAL MOBILITY INSERTS and DYNASTY® DUAL MOBILITY LINERS have shown to be substantially equivalent to the legally marketed predicate device cited in this premarket notification.