September 27, 2023

MicroPort Orthopedics Inc.
Ryan Ross
Senior Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K230563
Trade/Device Name: EVOLUTION® Hinge Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: August 25, 2023
Received: August 29, 2023

Dear Ryan Ross:

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,

Lixin Liu -S

Lixin Liu, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230563

Device Name

EVOLUTION® Hinge Knee System

Indications for Use *(Describe)*

The EVOLUTION® Hinge Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Hinge Knee System implants are for cemented use only.

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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510(k) Summary of Safety and Effectiveness

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 EVOLUTION® Hinge Knee System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 USA Phone: 866-872-0211 Fax: 855-446-2247
Date:	September 27, 2023
Contact Person:	Ryan Ross
Proprietary Name:	EVOLUTION® Hinge Knee System
Common Name:	Hinge Knee System
Classification Name and Reference:	21 CFR 888.3510 – Knee joint femorotibial metal/polymer constrained cemented prosthesis Class II
Review Panel and Subject Product Code:	Orthopedics/KRO
Predicate Device:	**GUARDIAN® Limb Salvage System**, K013035

Reference Devices:

EVOLUTION® Revision CCK Knee System, K171389
EVOLUTION® Revision Tibia Base System, K162026
EVOLUTION MP Revision Femur, EVOLUTION Femoral Augments, K142550
EVOLUTION® Stemmed CS Femur, K182125
EVOLUTION® MP Total Knee System, K093552
ADVANCE® Total Knee System – Patella, K122218
ULTRACK Total Knee System, K953439
ADVANCE® Revision CCK Knee System, K990030
ADVANCE® A-CLASS® Insert, K081479
REPIPHYSIS® Limb Salvage System, K021489
ADVANCE® Modular Tibial Component, K973524

DEVICE INFORMATION

A. Intended Use Statement

The EVOLUTION® Hinge Knee System is intended for use in total knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients. Indications for use are as follows:

Indications for Use
The EVOLUTION® Hinge Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Hinge Knee System implants are for cemented use only.

B. Device Description

The EVOLUTION® Hinge Knee System is a hinged, constrained cemented total knee system being introduced as a line extension to MicroPort Orthopedics Inc.'s EVOLUTION® Revision knee portfolio. The system is composed of:

- a femoral component offered in 7 sizes (sizes 2-8) with femoral yoke fixation screw for attachment to the yoke assembly
- a hinge yoke assembly offered in 9 sizes based on femur size (size 2-3, 4-6, and 7-8) and tibial insert thickness (small, medium, large)
- a yoke extension stop offered in 3 options (0°, 5°, 10°)
- a tibial insert offered in 8 sizes (sizes 1-8) and in 5 thickness options (12, 14, 17, 20, 24mm)
- a tibial base offered in two variants:
    - modular (8 sizes, 1-8) with tibia locking screw for attachment to stem extensions and stem extension adapters
    - monolithic (3 sizes, 1-3) with fixed small keel
- Offset adapters (2 sizes, 4mm x 25mm and 8mm x 25mm) and valgus stem adapters (2 sizes, 1° x 25mm and 2° x 25mm)
- Universal femoral augments
    - distal augments offered in 7 sizes (sizes B-H) in 4, 8, 12, 16, and 20mm thicknesses
    - posterior femoral augments in 7 sizes (sizes B-H) in 4, 8, and 12mm thicknesses,
- Medial and lateral tibial augments offered in 8 sizes (sizes 1-8) in 5, 10, and 15mm thicknesses

Components are manufactured from cobalt chrome alloy, titanium alloy, UHMWPE and crosslinked UHMWPE, and PEEK conforming to ASTM F75, F1537 - Alloy 1, F136, F648, F2026, respectively.

The system includes new and existing instrumentation from K140735, K162026, and K171389 to facilitate device implantation.

The subject femoral offset adapters and femoral valgus adapters are not for use with the EVOLUTION® Hinge tibial bases. The subject system is compatible with previously cleared stem extensions, stem extension adapters, and modular keels cleared in K162026 and patellae from K953439 and K122218. Furthermore, the subject universal femoral augments introduced in this 510(k) are backwards compatible with the EVOLUTION® Femurs cleared in K142550, K171389, and K182125.

C. Substantial Equivalence Discussion

The design features and materials of the subject device are substantially equivalent to those of the predicate device and reference devices. The indications for use and intended patient populations are identical to the predicate device. The fundamental scientific technology of the subject device has not changed relative to the predicate device. The safety and effectiveness of the subject device are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

Nonclinical testing results were used to support the performance and safety and effectiveness of the subject device and were compared to predicate device and reference device results.

- Tibial baseplate fatigue strength evaluation (cantilever bend and 3-point bend), including taper disassembly strength and fretting corrosion per ASTM F1800-19, ASTM F2083-21, ISO 14789-1:2000 and ISO 21536:2007
- Femoral taper fatigue strength, taper disassembly, and fretting corrosion evaluation per ASTM F2009-00
- Range of motion evaluation per ASTM F2083-12, ISO 21536 (2007), and as recommended per FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA issued on January 16, 2003
- Rotational stop evaluation per ASTM F2083-12 and ASTM F2722-21
- Fatigue strength, torsional stability, post-fatigue disassembly, and fretting corrosion analysis of the subject femoral valgus adapter per ASTM F2009-00 (2011)
- Femorotibial and patellofemoral contact area evaluation per FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA issued on January 16, 2003
- Wear and wear fatigue testing per ISO 14243-1 (2009), and particle analysis per ASTM F1877-16, ASTM F561-13, and ISO 17853-2011
- Anterior/Posterior shear fatigue evaluation of the subject construct
- Torque evaluation and compression testing of the subject femoral fixation screw per FDA Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Component Draft issued May 1995. Results were compared to non-predicate benchmarks.
- MRI safety evaluation per ASTM F2182-19 and FDA Guidance for "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices" issued March 2016, ASTM F2182-11a, ASTM F2181-11, ASTM F2052-15, ASTM F2213-17, and ASTM F2119-07 (reapproved 2013). Results were compared to non-predicate benchmarks.

Previous analyses were leveraged on the basis of feature equivalence to the reference devices:

- UHMWPE material property characterization
- Patellofemoral stability
- Femoral condylar fatigue

E. Clinical Testing

Clinical data were not provided for the subject device.

F. Biocompatibility

The subject device was evaluated for biological safety as guided by the applicable sections of ISO 10993-1:2018 and FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 4, 2020). All necessary biological endpoint testing was completed as needed per the standard. Based on the chemical characterization, endpoint testing, predicate performance, and overall biological risk assessment per ISO 10993-1:2018, the subject EVOLUTION® Hinge Knee System is concluded biocompatible.

G. 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 nonclinical testing, the subject EVOLUTION® Hinge Knee System has been shown to be substantially equivalent to the legally marketed predicate device cited in this premarket notification.