January 18, 2024

Microport Orthopedics, Inc.
Jonas Susaraba
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K233507
Trade/Device Name: EVOLUTION® Tibial Cones
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, KRO, PHX
Dated: October 24, 2023
Received: October 31, 2023

Dear Jonas Susaraba:

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,

Peter G. Allen -S Digitally signed by Peter G. Allen -S Date: 2024.01.18 18:01:42 -05'00'

For: 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)*

K233507

Device Name

EVOLUTION® Tibial Cones

Indications for Use *(Describe)*

The EVOLUTION® Tibial Cones are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory 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® Tibial Cones are for uncemented 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.

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

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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® Tibial Cones.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 USA Phone: 866-872-0211 Fax: 855-446-2247
Date:	January 18, 2024
Contact Person:	Jonas Susaraba
Proprietary Name:	EVOLUTION® Tibial Cones
Common Name:	Tibial Cone
Classification Name and Reference:	21 CFR 888.3565 Knee Joint Patellofemorotibial Metal/Polymer Porous Coated Uncemented Prothesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/MBH, JWH, KRO
Primary Predicate Device:	**Regenerex™ Porous Titanium Sleeve Augments,** K072336
Reference Devices:	**Evolution® Biofoam Tibial System,** K152298 **Evolution® Hinge Knee System,** K230563 **Arthrex Univers Revrs™ Porous Coated Baseplate and Universal Glenoid Inlay,** K182039 **LINK® TrabecuLink® Tibial Cones,** K200113

DEVICE INFORMATION

A. Intended Use/Indications for Use Statement

The EVOLUTION® Tibial Cones are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory 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® Tibial Cones are for uncemented use only.

B. Device Description

The EVOLUTION® Tibial Cones are hollow, cone shaped accessory implants made of a Titanium Alloy substrate conforming to ASTM F136 and has a diffusion-bonded porous coating on the inner and out surface made Titanium conforming to ASTM F67 (OsteoSync™ Ti). These cones are to be used in knee arthroplasty in skeletally mature patients as part of the tibial implant construct. The subject device is press-fit into a reamed tibial void and then filled with bone cement to provide a reinforced cement mantle for the compatible tibial construct.

The EVOLUTION® Tibial Cones consist of 6 sizes of porous cones to be used particularly for complex knee replacement cases where there is severe defect where the bone will not provide appropriate fixation for the EVOLUTION® implants. The subject device is stackable to a construct of maximum 3 compatible sizes.

Overall functionality and indications for use of the device are identical to the predicate device, Regenerex™ Porous Titanium Sleeve Augments (K072336). The subject device possesses similar design characteristics being a tapered cone implant of similar dimension with a porous coating to promote greater bone adhesion.

The subject EVOLUTION® Tibial Cones are compatible with the EVOLUTION® Revision Tibia components (K162026, K231947) and the EVOLUTION® Hinge Knee System modular tibial bases (K230563). This 510(k) also seeks to expand the compatibility of the cement keel (K231947) to also be used with the EVOLUTION® Hinge Modular Tibial Base (K230563) as they are used in conjunction with the subject EVOLUTION® Tibia Cones. The EVOLUTION® Hinge Modular Tibia Base possesses the same identical modular stem taper as the currently compatible EVOLUTION® Revision Tibia (K162026). Therefore, assessments presented in K231947 are sufficient to support the compatibility with EVOLUTION® Hinge Modular Tibia Base.

C. Substantial Equivalence Information

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

D. Nonclinical Testing

The following nonclinical testing was performed to support the performance of the subject device and was used as a basis for the determination of substantial equivalence:

- Porous coating evaluation according to the FDA guidance, "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement, dated April 28, 1994.

- Abrasion Resistance testing per ASTM F1978-22.
- Tensile Strength Testing per ASTM F1147-05
- Static Shear Strength Testing per ASTM F1044-05
- Shear Fatigue Testing per ASTM F1160-14
- Modified surface evaluation per ASTM F1854-09. This standard was used to determine pore diameter, minimum void intercept length, and mean volume percent of voids.
- 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. Food and Drug Administration”," issued March 2018, ASTM F2182-11a, ASTM F2181-11, ASTM F2052-15, ASTM F2213-17, and ASTM F2119-07 (reapproved 2013).

E. Clinical Testing

Clinical data was not submitted or relied on for a determination of substantial equivalence.

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 2023). All necessary biological endpoint testing was completed as needed per the standard. Based on the material composition data, endpoint testing, and overall biological risk assessment per ISO 10993-1:2018, the subject EVOLUTION® Tibial Cones 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® Tibial Cones, is as safe and effective and performs as well or better than the legally marketed predicate and reference devices.