August 21, 2026

Microport Orthopedics, Inc.
Jonas Susaraba
Senior Regulatory Affairs Specialist
5677 Airline Rd.
Arlington, Tennessee 38002

Re: K253728
Trade/Device Name: Evolution® AM BIOFOAM® Tibial System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: July 21, 2026
Received: July 21, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253728

Device Name
EVOLUTION® AM BIOFOAM® Tibial System

Indications for Use *(Describe)*
The EVOLUTION® AM BIOFOAM® Tibial System is 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® AM BIOFOAM® Tibial System is for uncemented use only.

The EVOLUTION® AM BIOFOAM® Tibial System can be implanted using the Kinematic Alignment technique. When the Kinematic Alignment approach is utilized, the devices are indicated for 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

The Evolution® Kinematic Alignment technique may only be used with Evolution® Primary knee components or the Evolution® Stemmed CS Femur.

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.

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® AM BIOFOAM® Tibial System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 USA Phone: 866-872-0211 Fax: 855-446-2247
Date:	August 21, 2026
Contact Person:	Jonas Susaraba
Proprietary Name:	EVOLUTION® AM BIOFOAM® Tibial System
Common Name:	Total Knee Replacement System
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
Primary Predicate Device:	**EVOLUTION® BIOFOAM® Tibial System,** K152298
Secondary Predicate Device:	**EVOLUTION® Total Knee Systems – Kinematic Alignment Instrumentation and Technique,** K243574
Reference Devices:	**EVOLUTION® MP Total Knee System,** K093552 **EVOLUTION® MP Total Knee System,** K102380 **ADVANCE® Modular Tibial Component,** K973524 **EVOLUTION® MP CS/CR Porous Femur,** K140735 **Prime and DYNASTY® Additive Manufacturing Shells,** K202705

MicroPort Orthopedics

DEVICE INFORMATION

A. Intended Use/Indications for Use Statement

The EVOLUTION® AM BIOFOAM® Tibial System is 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® AM BIOFOAM® Tibial System is for uncemented use only.

The EVOLUTION® AM BIOFOAM® Tibial System can be implanted using the Kinematic Alignment technique. When the Kinematic Alignment approach is utilized, the devices are indicated for 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

The Evolution® Kinematic Alignment technique may only be used with Evolution® Primary knee components or the Evolution® Stemmed CS Femur.

MicroPort Orthopedics

B. Device Description

The EVOLUTION® AM BIOFOAM® Tibial System is a proximal tibial implant component to be used in total knee arthroplasty and a line extension to the EVOLUTION® product family. It is based on modifications to the predicate EVOLUTION® BIOFOAM® Tibial System (K152298) and is offered with and without screw holes in 11 sizes (1-8, 2+, 6+, and 8+) in left and right versions which are identical to the primary predicate EVOLUTION® BIOFOAM® Tibial System (K152298). Unlike the predicate device which is a two-piece design consisting of a tibial base and a modular keel, the subject tibial system is a single piece design that includes a tibial tray and an integrated keel that has identical geometry to the assembled predicate tibial base and modular keel. Like its primary predicate, the subject device is made from a titanium alloy (Ti6Al4V). In contrast, the subject device utilizes additive manufacturing methods to produce the device.

The subject EVOLUTION® AM BIOFOAM® Tibial System has a substantially equivalent design, substrate and coating morphology, material, overall form, lock detail geometry, intended use, implantation methods, component, accessory compatibility, and patient contact type/duration as the predicate device.

C. Technological Comparison

The subject EVOLUTION® AM BIOFOAM® Tibial System is a proximal tibial implant component intended for use in total knee arthroplasty and is a line extension of the EVOLUTION® product family. The subject device is substantially equivalent to the primary predicate EVOLUTION® BIOFOAM® Tibial System (K152298) with respect to intended use, implant sizing and configurations, overall form, articular interface geometry, keel geometry, locking mechanism, fixation spike locations, material composition (Ti-6Al-4V titanium alloy), implantation method, component compatibility, and patient contact type and duration.

The subject device differs from the primary predicate in that it utilizes a single-piece construction consisting of a tibial tray with an integrated keel, whereas the predicate device utilizes a two-piece design consisting of a tibial base and modular keel. The geometry of the integrated keel is identical to the geometry of the assembled tibial base and modular keel of the predicate device. In addition, the subject device utilizes additive manufacturing technology during production, whereas the predicate device is manufactured using conventional manufacturing methods.

These technological differences do not alter the intended use, implant interfaces, or clinical function of the device. Performance testing and engineering analyses demonstrate that the subject device performs as intended and is substantially equivalent to the predicate device.

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:

- Cantilever Fatigue Testing per ASTM F1800

- Biocompatibility Testing per ISO 10993-1
- Static Tensile Testing per ASTM F1147
- Lap Shear Testing per ASTM F1160
- Compression Testing per ASTM E9
- Abrasion Resistance Testing per ASTM F1978
- 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.
- 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).- Biocompatibility testing per ISO 10993-1 (2018), ISO 10993-5 (2009), ISO 10993-10 (2014), ISO 10993-11 (2017), ISO/TS 21726 (2019), 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" (June 16th 2016)

Previous analysis leveraged for this application due to equivalency include: Lock detail assessment.

The nonclinical performance testing results demonstrate that the device is as safe and effective and performs as well or better than the legally marketed predicate devices.

E. Clinical Testing

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

F. Conclusion

The design features, materials information, performance testing and data analysis provided in this premarket notification adequately support the substantial equivalence of the EVOLUTION® AM BIOFOAM® Tibial System with the predicates.