February 18, 2025

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

Re: K243574
Trade/Device Name: Evolution® Total Knee Systems - Kinematic Alignment Instrumentation and Technique
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: November 14, 2024
Received: November 19, 2024

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 (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.

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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K243574

Device Name

Evolution® Total Knee Systems - Kinematic Alignment Instrumentation and Technique

Indications for Use *(Describe)*

The Evolution® Total Knee Systems can be implanted using the Kinematic Alignment technique. When the Kinematic Alignment approach is utilized, the devices are indicated for 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;

The Evolution® Kinematic Alignment technique may only be used with Evolution® Primary Knee components or the Evolution® Stemmed CS Femur and Evolution® Revision Tibia Base.

Type of Use *(Select one* or *both,* as *applicable)*

[X] 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) #:

510(k) Summary

Prepared on: 2024-11-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MicroPort Orthopedics Inc.
Applicant Address	5677 Airline Road Arlington TN 38002 United States
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Applicant Contact	Mr. Ryan Ross
Applicant Contact Email	ryan.ross@ortho.microport.com
Correspondent Name	MicroPort Orthopedics Inc.
Correspondent Address	5677 Airline Road Arlington TN 38002 United States
Correspondent Contact Telephone	901-867-4401
Correspondent Contact	Mr. Ryan Ross
Correspondent Contact Email	ryan.ross@ortho.microport.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Evolution® Total Knee Systems - Kinematic Alignment Instrumentation and Technique
Common Name	Total Knee Replacement
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3560, 21 CFR 888.3565
Product Code(s)	JWH, MBH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K1 40 73 5	Evolution® MP CS/CR Porous Femur	MB H
K09 3 552	Evolution® MP Total Knee System	J WH
K1 02 3 8 0	Evolution® MP Total Knee System	J WH
K152298	Evolution® Biofoam® Tibia Base and Modular Keels	MBH
K162026	Evolution® Revision Tibia Base System	JWH
K170288	Evolution® Biofoam® Tibia Base with Biofoam® Additive Manufa	MBH

K182125	Evolution® Stemmed CS Femur	JWH
K182251	Evolution® NitrX™ Medial-Pivot Knee	JWH
K173890	GMK Sphere - Kinematic Alignment	JWH
K172524	Zimmer Persona Personalized Knee System	MBH

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to seek clearance for the Evolution® Total Knee System Kinematic Alignment Instrumentation and Technique. The instruments consist of resection and alignment guides, shims, gauges, calipers, spacers, and trays that are used in conjunction with MicroPort's existing 510(k)-cleared knee instrumentation. The objective of the Kinematic Alignment technique is to duplicate the pre-arthritic native joint line. Unlike Mechanical Alignment where the focus is placed on making a perpendicular tibial resection, non-anatomic distal and posterior femoral cuts, and ligament releases if needed, Kinematic Alignment prioritizes the femoral cuts to replicate the native joint line. The Kinematic Alignment technique compensates for wear on the femur to attain the prearthritic joint line and strives for natural ligament tension.

The Evolution® Kinematic Alignment surgical technique is used with the following 510(k)-cleared knee components. No changes to the compatible Evolution® implants are being presented in this 510(k). The compatible implants are exactly the same as the previously cleared Evolution® implants.

- Evolution® MP Total Knee System, K093552
- Evolution® MP Total Knee System, K102380
- Evolution® MP CS/CR Porous Femur, K140735
- Evolution® Biofoam® Tibial Base and Evolution Biofoam Modular Keels, K152298
- Evolution® Revision Tibia Base System, K162026
- Evolution® Biofoam Tibial Base with Biofoam® Additive Manufacturing, K170288
- Evolution® Stemmed CS Femur, K182125
- Evolution® NitrX™ Medial-Pivot Knee, K182251

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Evolution® Total Knee Systems can be implanted using the Kinematic Alignment technique. When the Kinematic Alignment approach is utilized, the devices are indicated for 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;

The Evolution® Kinematic Alignment technique may only be used with Evolution® Primary Knee components or the Evolution® Stemmed CS Femur and Evolution® Revision Tibia Base.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject and predicate devices have the same intended use. Indications for use remain nearly identical.

Technological Comparison

21 CFR 807.92(a)(6)

The subject devices possess similar technological characteristics as the predicate and reference devices. Overall design, materials of construction, principles of operation, and fundamental scientific technology remain identical. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information and analyses provided within this Premarket Notification.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance testing conducted on the predicate and reference devices are being leveraged in support of this submission:

- Range of Motion
- Tibiofemoral Stability
- Patellofemoral Stability

Risks were identified based on the proposed surgical technique and were mitigated by technical rationales in comparison to predicate testing:

- Resection Angle Comparison
- Range of Motion
- Force Analysis
- Tibiofemoral Stability
- Patellofemoral Stability
- Wear

The subject Kinematic Alignment instruments underwent cadaveric validation of the surgical technique and associated instrumentation.

Not applicable. Clinical data were not necessary for the subject device.

The nonclinical analyses and validations demonstrate that the device is as safe and effective and performs as well or better than the legally marketed predicate and reference devices.