October 29, 2026

Suzhou Microport Orthorecon Co., Ltd.
Hongxing Qiu
Regulatory Affairs Senior Manager
Bldg. 2 and 3, #151, Fengli St., Suzhou Industrial Park China (Jiangsu)
Pilot Free Trade Zone Suzhou District Park China (Jiangsu)
Suzhou, Jiangsu Province 215000
China

Re: K263065
Trade/Device Name: MicroPort Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: JWH, HRY
Dated: September 1, 2026
Received: September 1, 2026

Dear Hongxing Qiu:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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: 2026.10.29 12:55:33 -04'00'

for Lixin Liu, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263065

Please provide the device trade name(s).

MicroPort Total Knee System

Please provide your Indications for Use below.

The MicroPort Total 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 MicroPort Total Knee System is for cemented use only.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

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 the MicroPort Total Knee System.

Submitted by:	Suzhou MicroPort OrthoRecon Co., Ltd. Building 2 and 3, NO.151, Fengli Street, Suzhou Industrial Park China (Jiangsu) Pilot Free Trade Zone Suzhou District, 215000 Suzhou, Jiangsu, China Phone: 86-0512-65001777
Date:	October 19, 2026
Contact Person:	Hongxing Qiu
Proprietary Name:	MicroPort Total Knee System
Common Name:	Total Knee System
Classification Name and Reference:	Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis Class II
Regulation Number:	21 CFR 888.3560 21 CFR 888.3530
Review Panel and Subject Product Code:	Orthopedics/87/JWH, HRY
Predicate Device:	MedalOne Total Knee System (EVOLUTION MPX™), K244039
Reference Devices:	ADVANCE KNEE SYSTEM (K972626) ADVANCE ULTRA-CONGRUENT TIBIAL INSERT (K972770) ADVANCE STATURE FEMORAL COMPONENT (K063731) EVOLUTION™ MP Total Knee System (K093552)

EVOLUTION MP ADAPTIVE PS TIBIAL INSERT (K131679)
EVOLUTION MP CS/CR POROUS FEMUR/EVOLUTION ADAPTIVE CS AND PS INSERTS (K140735)

Device Description Summary

The subject MicroPort Total Knee System is a cemented, semi-constrained total knee replacement system intended to reduce or relieve pain and improve knee function. The system is presented in two related configurations — a Cruciate Substituting (CS) System and a Posterior Stabilized (PS) System — that share a common Tibial Baseplate. The CS System is based on the ADVANCE® Knee System design lineage, and the PS System is based on the EVOLUTION® MP Adaptive PS design lineage. The predicate device is the MedalOne Total Knee System (EVOLUTION MPX™, K244039).

The subject system comprises the following implantable components: CS femoral components (sizes 1–6, intermediate sizes 1A–3A, and narrow STATURE™ sizes 2–4, left and right); PS femoral components (sizes 1–8, left and right); CS tibial inserts (sizes 1–6 with intermediate sizes 1A–3A, in thicknesses of 10, 12, 14, 17, 20 and 25 mm; 10–20 mm for size 6); PS tibial inserts (sizes 2/1 through 7/5, in thicknesses of 10, 12, 14, 17 and 20 mm); non-porous tibial baseplates (standard sizes 1–6 and oversize sizes 1+ through 5+).

The femoral components and tibial baseplates are made from cast cobalt-chromium-molybdenum alloy conforming to ISO 5832-4. The tibial inserts are made from UHMWPE Type 1 (GUR 1020) conforming to ISO 5834-2. All implant components are intended for cemented use with bone cement.

Except for the additional intermediate femoral sizes (1A, 2A, 3A), the additional 25 mm CS insert thickness, and the PS configuration components, the subject components have the same critical technological characteristics as their corresponding predicate or reference-device components. The new sizes and components are identical to or bounded by the corresponding cleared ADVANCE and EVOLUTION® MP reference devices.

The system also includes reusable instrumentation, including device-specific instruments (trials, resection guides, gauges, and sizing calipers) and general instruments (drivers and trays). The subject instruments have the same intended use, materials, and manufacturing steps as the corresponding predicate instruments, and the subject implants may be implanted using either the new subject-labeled instruments or compatible predicate instrumentation.

Intended Use/Indication for Use

The MicroPort Total 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 MicroPort Total Knee System is for cemented use only.

Indication for Use Comparison

Subject indications for use are identical to those of the predicate device, the MedalOne Total Knee System (K244039).

Technological Comparison

The indications for use, intended patient population, and fundamental scientific technology of the subject devices are the same as those of the predicate device and reference devices. Except for the additional intermediate femoral sizes (1A, 2A, 3A), the additional 25 mm CS insert thickness, and the PS configuration components, the subject components have the same critical technological characteristics as their corresponding predicate or reference-device components, and no new worst-case scenarios are introduced. The technological characteristics of the subject devices are supported by the bench performance testing provided in this submission.

The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification submission.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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:

- Biocompatibility and endotoxin testing per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO/TS 21726, and the FDA guidance "Use of International Standard ISO 10993-1" (September 8, 2023);

- Tibial baseplate fatigue strength per ISO 14879-1.
- UHMWPE tibial insert wear per the ISO 14243 series.
- UHMWPE material property characterization per the ISO 5834 series after accelerated aging;
- Range of motion evaluation by CAD simulation per ASTM F2083;
- Femorotibial constraint and stability testing per ASTM F1223 and ASTM F2083;
- Femorotibial contact area evaluation;
- Component interlock strength testing of the tibial insert–tibial baseplate interface.
- Static and fatigue strength of the femoral components per ISO 21536:2023;
- Shelf life evaluation;.

The following previous analyses were leveraged based on equivalence to the predicate device (K244039) and applicable reference devices:

- Posterior-stabilized tibial post performance;
- Durability of the patellofemoral joint;
- UHMWPE tibial insert endurance and deformation under high flexion; and
- MRI safety evaluation;

Justification was provided for not completing additional posterior-stabilized tibial post shear, patellofemoral durability, and high-flexion endurance testing, based on the design equivalence to the predicate and reference devices described above. Clinical data were not relied on for a determination of substantial equivalence.

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 and reference devices.