September 10, 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, 215000 Suzhou, Jiangsu Province
China

Re: K262293
Trade/Device Name: EVOLUTION MPX™ 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: July 7, 2026
Received: July 7, 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.

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.09.10 22:10:46 -04'00'

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

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.	K262293

Please provide the device trade name(s).

EVOLUTION MPX™ Total Knee System

Please provide your Indications for Use below.

The EVOLUTION MPX™ 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 EVOLUTION MPX™ 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 EVOLUTION MPX™ 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:	August 11, 2026
Contact Person:	Hongxing Qiu
Proprietary Name:	EVOLUTION MPX™ Total Knee System
Common Name:	Total Knee System
Classification Name and Class:	Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis; Class II
Regulation Number:	21 CFR 888.3560
Review Panel and Subject Product Codes:	Orthopedics/87 JWH, HRY
Predicate Device:	EVOLUTION® MP Total Knee System, K093552

Reference Devices: EVOLUTION® MP Total Knee System, K102380
ULTRACK TOTAL KNEE SYSTEM, K953439
MedalOne Total Knee System, K244039

Device Description Summary

The subject, EVOLUTION MPX™ Total Knee System, is intended for reduction or relief of pain and/or improved knee function. The subject submission is a line extension to the previously cleared MedalOne Total Knee System (K244039), which has since been rebranded as the EVOLUTION MPX™ Total Knee System; no changes have been made to the device other than the proprietary name. The subject submission incorporates previously cleared system components from K244039 (CS/CR Femur, CS Insert, Tibia Base, and Patellas) in addition to the new components described herein. The current submission adds PS Femoral Components, CR Tibial Inserts, PS Tibial Inserts, additional 11 mm, 13 mm, and 15 mm thickness options for CS, CR, and PS Tibial Inserts, and additional SoSuperior Patella sizes (38 mm and 41 mm).

The subject system is based on, and substantially equivalent to, the predicate Evolution® MP Total Knee System in terms of geometry, nominal dimensions, manufacturing tolerances, overall device processing steps, materials of construction, sizing options, and interchangeabilities. The PS femoral components are made from Cast CoCr Alloy conforming to ISO 5832-4 and are offered in sizes 1-8 in left and right variants. The CS/CR/PS tibial inserts are made from standard UHMWPE (Type 1) conforming to ISO 5834-2. Three additional intermediate thickness options of 11 mm, 13 mm and 15 mm are introduced to CS tibial inserts. CR tibial inserts are available in sizes 1-8 and plus sizes 2 and 6, with thickness options of 10, 11, 12, 13, 14, 15, and 17mm. PS tibial inserts are available in sizes 1-8 and plus sizes 2 and 6, with thickness options of 10, 11, 12, 13, 14, 15, 17, 20, and 24mm. The patellas are made from UHMWPE conforming to ISO 5834-2 and are offered in a tri-peg design in 2 additional sizes: 38 and 41 mm. The subject 38 mm and 41 mm SoSuperior Patella sizes are substantially equivalent to the corresponding patellar components cleared under K953439 and are identical with

respect to design, dimensions, material composition, intended use, and performance characteristics. Differences are limited to manufacturer-specific attributes that do not affect the device's technological characteristics or performance.

The system is intended to be used with bone cement for fixation.

The system also includes device-specific instrumentation to facilitate implantation of the subject devices. The instrument system includes new EVOLUTION MPX™ instrumentation and is also fully compatible with the predicate Evolution instrumentation.

Intended Use/Indication for Use

The EVOLUTION MPX™ 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 EVOLUTION MPX™ Total Knee System is for cemented use only.

Indication for Use Comparison

Subject indications for use are the same as the predicate.

Technological Comparison

The indications for use, intended patient population, and fundamental scientific technology of the subject devices are identical to those of the predicate device and reference devices. The design features of the subject devices are substantially equivalent to those of the predicate device and do not create any new worst-case scenarios. The difference in

technological characteristics of the device does not raise different questions of safety and effectiveness. The substantial equivalence is supported through bench testing results provided in the scope of this application.

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:

- 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", March 22, 2016, ASTM F2182 - 11a and FDA Guidance Document, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", 10 Oct 2023, ASTM F2182-11a, ASTM F2181-11, ASTM F2052-21, ASTM F2213-17, and ASTM F2119-24.

- 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" (September 8, 2023)
- Endotoxin Testing

The following previous analyses were leveraged from applicable predicate (K093552) and reference devices:

- Range of motion evaluation
- Femorotibial and patellofemoral contact area and stability evaluation
- Component lock detail evaluation
- UHMWPE Material Property Characterization
- Durability of the Patellofemoral Joint
- UHMWPE Tibial Insert Endurance and Deformation Under High Flexion
- Fatigue Strength of Knee Femoral Components

Justification was provided for not completing wear testing of the tibial bearing components.

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.