February 28, 2025

Suzhou MicroPort OrthoRecon Co., Ltd.
Yujian Mao
Quality & RA Senior Director
Building 2 and 3, NO.151, Fengli Street, Suzhou Industrial Park
Pilot Free Trade Zone Suzhou District
Suzhou, Jiangsu 215000
China

Re: K244039
Trade/Device Name: MedalOne 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 Code: JWH, HRY
Dated: December 12, 2024
Received: December 30, 2024

Dear Yujian Mao:

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

Submission Number *(if known)*

K244039

Device Name

MedalOne Total Knee System

Indications for Use *(Describe)*

The MedalOne 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 MedalOne Total Knee System is for cemented 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 MedalOne 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:	January 17, 2025
Contact Person:	Qingling Bao
Proprietary Name:	MedalOne 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:	EVOLUTION® MP Total Knee System, K093552
Reference Devices:	EVOLUTION® MP Total Knee System, K102380 ADVANCE® All-Poly Onlay 3-Peg Patella, K953439 ADVANCE® Total Knee System-Patella, K122218

Device Description Summary

The subject device, MedalOne Total Knee System, is intended for reduction or relief of pain and/or improved knee function. The subject device is a total knee replacement system composed of four different component types: MedalOne Femoral Component, MedalOne CS Tibial Insert, MedalOne Tibial Base and SoSuperior Patella.

The subject system is based on, and substantially equivalent to, the predicate EVOLUTION® MP Total Knee System in terms of size availability, geometry, nominal dimensions, manufacturing tolerances, overall device processing steps, and materials of construction. The articulation adheres to the same "Medial-Pivot" philosophy as the predicate device. The femoral components are made from Cobalt Chrome alloy conforming to ISO 5832-4 and are offered in sizes 1-8 in left and right variants. The tibial inserts are made from standard UHMWPE conforming to ISO 5834-2 and are available in sizes 1-8 in standard and "extended" versions with thickness options of 10, 12, 14, 17, 20, and 24mm. The tibial bases are made from Cobalt Chrome alloy conforming to ISO 5832-4 and are available in 8 standard sizes and 3 plus sizes to permit 1-up/1-down size interchangeability. The patellas are made from UHMWPE conforming to ISO 5834-2 and are offered in a tri-peg design in 4 sizes: 26, 29, 32, and 35mm. 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 MedalOne instrumentation and is fully compatible with the predicate Evolution instrumentation.

Intended Use/Indication for Use

The MedalOne 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 MedalOne 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 the primary and other predicate devices. The design features of the subject devices are substantially equivalent to those of the predicate devices and do not create any new worst-case scenarios. The difference in technological characteristics of the devices 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:

- Tibial baseplate fatigue strength evaluation per ISO 14789-1:2000

- 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" issued March 2016, 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" (September 8, 2023)
- Endotoxin Testing

The following analyses were leveraged based on substantial equivalence to the predicate device:

- Range of motion evaluation
- Femorotibial and patellofemoral contact area and stability evaluation
- Component lock detail evaluation
- UHWMPE 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 provided and not necessary to support the substantial equivalence of subject device with the predicate device.

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.