



October 24, 2025

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Shing Jen Tai
Principal Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K252044

Trade/Device Name: Triathlon® Total Knee System - Triathlon® Gold Femoral Components

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dated: June 30, 2025

Received: September 25, 2025

Dear Shing Jen Tai:

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

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.

K252044

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Please provide the device trade name(s).

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Triathlon® Total Knee System - Triathlon® Gold Femoral Components

Please provide your Indications for Use below.

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General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques

The Triathlon® Gold Femoral Components are indicated for both uncemented and cemented use.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Shing Jen Tai
Principal Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
269-800-2088
Shingjen.tai@stryker.com

Alternate Contact Margaret Klippel
Chief Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
201-831-5559
Margaret.klippel@stryker.com

Date Prepared: June 30, 2025

Proprietary Name: Triathlon[®] Total Knee System – Triathlon[®] Gold Femoral Components

Common Name: Total Knee Joint Replacement Prosthesis

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR 888.3565)

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

Product Codes: MBH; JWH

Legally Marketed Primary and Additional Predicate Devices to Which Substantial Equivalence is Claimed:

- Triathlon™ Total Knee System - K051380 (Primary Predicate)
- Omni TiN Coated Apex Knee™ System - K191765 (Additional predicate)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® Tritanium® Tibial Baseplates – K123486
- Exactech Truliant® Porous Tibial Tray and Alteon Bone Screws – K182346
- Biocore9 Acetabular Cup System - K212761
- Endotec B-P Hemispherical Acetabular Component - K963101
- Trident® II Tritanium® Acetabular Shells and 6.5mm Low Profile Hex Screw - K161569
- Smith & Nephew Legion Primary Knee System - K093746

Reason for 510(k) Submission:

The purpose of this Traditional 510(k) Premarket Notification is to introduce the new Triathlon® Gold Femoral Components as a line extension of the previously cleared Triathlon® cruciate retaining (CR) femoral components within the Triathlon® Total Knee System. This submission proposes adding the Triathlon® Gold Femoral Components to the system as an additional CR femoral component option that is 1) manufactured from titanium alloy (Ti-6Al-4V) and fully coated with Titanium Nitride (TiN), and 2) for uncemented and cemented use. Addition of these femoral components does not change the intended use, indications for use, operational principles, or fundamental scientific technology of the Triathlon® Total Knee System.

Device Description:

The Triathlon® Total Knee System is a total knee prosthesis designed to resurface the articulating surface of the femoral and tibial bones. In a total knee replacement, Triathlon® Gold Femoral Components are intended to replace the articulating surface of the distal femur and articulate against an articular surface of the tibial component as well as an optional patellar component. Triathlon® Gold Femoral Components are additively manufactured from Ti-6Al-4V powder, using Electron Beam Melting (EBM) technology, and then fully coated with titanium nitride (TiN), using Physical Vapor Deposition (PVD). In addition to TiN coating, the bone cut facing surfaces of these femoral components contain the Tritanium® porous structure. Indicated for both uncemented and cemented use, the subject femoral components are provided in right and left configurations and eight proportional sizes (sizes 1-8) for a total of 16 unique components to accommodate differences in patient anatomy. The subject femoral components are sterile, single use devices.

Intended Use:

The subject device is intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function.

Indications for Use:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques

The Triathlon® Gold Femoral Components are indicated for both uncemented and cemented use.

Summary of Technological Characteristics:

The device comparisons and performance testing show that the subject Triathlon® Total Knee System – Triathlon® Gold Femoral Components are substantially equivalent to the predicate devices based on intended use, indications for use, design, materials, technical and performance characteristics, and operational principles that do not raise different questions of safety and effectiveness.

Non-Clinical Testing:

The following non-clinical laboratory testing and engineering analyses were performed to determine substantial equivalence:

- Physical characterization of the porous surfaces
- Chemical characterization of the porous surfaces
- Mechanical characterization of the porous surfaces
- Chemical characterization of the solid surface
- Mechanical characterization of the solid surface
- Characterization of TiN coating
- Femoral fatigue testing
- Coating adhesion verification testing
- Tibial-femoral and patella-femoral engineering analyses
- Femoral backside engineering analysis
- Clean wear testing
- Third body wear testing

- MRI Safety testing
- Biocompatibility evaluation

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion:

The subject Triathlon® Total Knee System – Triathlon® Gold Femoral Components are substantially equivalent to the primary predicate Triathlon™ Total Knee System (K051380) and additional predicate Omni TiN Coated Apex Knee™ System (K191765) based on intended use, indications for use, design, material, technological characteristics, operational principles, and non-clinical performance data that do not raise different questions of safety and effectiveness.