February 18, 2026

Howmedica Osteonics Corp., Dba Stryker Orthopaedics
Nora Armstrong
Principal Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K253637
Trade/Device Name: Triathlon® Total Knee System - Triathlon® X3® Medial Stabilized Tibial Bearing Insert
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: November 18, 2025
Received: November 19, 2025

Dear Nora Armstrong:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.02.18 16:02:07 -05'00'

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.	K253637

Please provide the device trade name(s).

TRIATHLON® TOTAL KNEE SYSTEM - Triathlon® X3® Medial Stabilized Tibial Bearing Insert

Please provide your Indications for Use below.

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.
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.

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

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

510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Nora Armstrong Principal Regulatory Affairs Specialist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 +353-1-6800256 nora.armstrong@stryker.com
Alternate Contact	Shing Jen Tai Principal Regulatory Affairs Specialist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 269-800-2088 shingjen.tai@stryker.com
Date Prepared:	February 16, 2026
Proprietary Name:	Triathlon® Total Knee System – Triathlon® X3® Medial Stabilized Tibial Bearing Insert
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® X3® CS Tibial Bearing Insert - K242831 (Primary Predicate)
- Triathlon® X3® PS Tibial Bearing Insert - K242831 (Additional Predicate)
- Persona® Medial Congruent Bearing Insert - K243293 (Additional Predicate)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® CS Tibial Bearing Insert - K242831: Wear performance
- Trident® II Tritanium® Acetabular Shell - K250989: Material properties in fretting corrosion analysis
- Exeter X3® RimFit Cup - K240418: Material evaluation for biocompatibility

Reason for 510(k) Submission:
The purpose of this Traditional 510(k) Premarket Notification is to introduce the new Triathlon® X3® Medial Stabilized Tibial Bearing Insert to the Triathlon® Total Knee System. This submission proposes adding the Triathlon® X3® Medial Stabilized Tibial Bearing Insert to the system as a tibial bearing insert option with an asymmetric articulating surface that is designed to increase medial conformity with the compatible femoral components. Addition of this tibial bearing insert does not change the intended use, indications for use, operational principles, or fundamental scientific technology of the Triathlon® Total Knee System.

Device Description:
The subject device is a sterile, single use device that is intended for use in primary or revision total knee arthroplasty with previously cleared Triathlon® femoral and tibial baseplate components. The subject device adds to the Triathlon® Total Knee System a tibial bearing insert option with an asymmetric articulating surface which is designed to increase medial conformity with the compatible femoral components. The design is intended to provide increased sagittal stability and allow for more natural rotational kinematics. This tibial bearing insert also introduces a material change to the locking wire subcomponent located on the anterior portion of the distal baseplate mating profile. The locking wire component is intended to assemble the insert with a compatible tibial baseplate. The locking wire provided with the Triathlon® X3® Medial Stabilized Tibial Bearing Insert is made from titanium alloy (Ti-6Al-4V).

Intended Use:
The subject device is intended for primary or revision total knee arthroplasty.

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.
- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Summary of Technological Characteristics:

The device comparisons and performance testing show that the subject Triathlon® X3® Medial Stabilized Tibial Bearing Insert is 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:

- Material Characterization – UHMWPE
- Contact Area/Contact Stress Analysis
- Range of Motion Analysis
- Range of Constraint Analysis
- Wear Testing
- Locking Wire Static Disassembly Retention Strength Test
- A/P & M/L Shear
- Fretting Corrosion Analysis
- MRI Evaluations:
    - Magnetically induced displacement force (ASTM F2052-21)
    - Magnetically induced torque (ASTM F2213-17)
    - Image artifact (ASTM F2119-24)
    - RF Heating evaluation (ASTM F2182-19e2)
- Biocompatibility evaluated per ISO 10993-1:2020
- Shelf-life validated per the following standards:

  - ISO 11607-1:2019
  - ISO 11607-2:2019
  - ASTM F1980-21
  - Testing performed per the following methods:
    - ASTM F1886/F1886M-16
    - ASTM F88/88M-21
    - ASTM F2096-11(2019)
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2019 was used for pyrogenicity testing to achieve an endotoxin limit of < 20EU/Device.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion:

The subject Triathlon® X3® Medial Stabilized Tibial Bearing Insert is substantially equivalent to the primary predicate Triathlon® X3® CS Tibial Bearing Insert (K242831) and additional predicate devices Triathlon® X3® PS Tibial Bearing Insert (K242831) and Persona® Medial Congruent Bearing Insert (K243293) 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.