December 4, 2024

Stryker Orthopaedics
Connor Tighe
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K242831
Trade/Device Name: Triathlon Knee System; Triathlon Pro Posterior Stabilized Femoral Components; Triathlon Tritanium Tibial Baseplate; Triathlon Low Profile Tibial Tray; Triathlon Metal Backed Patella; Triathlon Partial Knee System; Avon Patello-femoral Joint Prosthesis; Restoris Multi-Compartmental 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, KRR, MBH, NPJ, HRY, HSX
Dated: September 18, 2024
Received: September 19, 2024

Dear Connor Tighe:

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Knee System

Indications for Use *(Describe)*

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® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.
The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.
The Triathlon® All Polyethylene tibial components are indicated for cemented use only.
Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:
• Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:
• Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
• Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:
• Severe degeneration or trauma requiring extensive resection and replacement
• Femoral and Tibial bone voids
• Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Pro Posterior Stabilized Femoral Components

Indications for Use *(Describe)*

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.
Additional Indications for Posterior Stabilized (PS) components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.
The Triathlon® Pro PS Femoral Components are intended 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Tritanium Tibial Baseplate

Indications for Use *(Describe)*

General Total Knee Arthroplasty (TKR) Indications:
• Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid 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

Additional General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament
• Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Low Profile Tibial Tray

Indications for Use *(Describe)*

The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon® femoral components and associated patellar components, and tibial bearing inserts in primary cemented total knee arthroplasty. The indications for the Triathlon® Low Profile Tibial Tray are outlined below:
Indications for Use:
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Metal Backed Patella

Indications for Use *(Describe)*

• Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed;
• Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
• Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Triathlon Partial Knee System

Indications for Use *(Describe)*

Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
• Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
• As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
• Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.
These components are intended for implantation with bone cement.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Avon Patello-femoral Joint Prosthesis

Indications for Use *(Describe)*

The Avon Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity, or dysfunction persists. These components are single use only and are intended for implantation with bone cement.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K242831

Device Name
Restoris Multi-Compartmental Knee System

Indications for Use *(Describe)*

Restoris MCK is indicated for single or multi-compartmental knee replacement used in conjunction with RIO, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces.
The specific knee replacement configurations include:
• Medial unicondylar
• Lateral unicondylar
• Patellofemoral
• Medial bi-compartmental (medial unicondylar and patellofemoral)
Restoris Multi Compartmental Knee is for single use only and is intended for implantation with bone cement.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Connor Tighe
Staff Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
+1 201-831-5069

Alternate Contact Margaret Klippel
Chief Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
(201) 831-5559

Date Prepared: December 4, 2024

Proprietary Name: Triathlon Knee System; Triathlon Pro Posterior Stabilized Femoral Components; Triathlon Tritanium Tibial Baseplate; Triathlon Low Profile Tibial Tray; Triathlon Metal Backed Patella; Triathlon Partial Knee System; Avon Patello-femoral Joint Prosthesis; Restoris Multi-Compartmental Knee System

Common Name: Artificial Knee Replacement Components - Femoral, tibial and patellar

Classification Name:

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3560

Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis. 21 CFR §888.3540

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. 21 CFR §888.3565

Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3530

Knee joint femorotibial metal/polymer non-constrained cemented prosthesis. 21 CFR §888.3520

Product Codes:

JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer

KRR - prosthesis, knee, patello/femoral, semi-constrained, cemented, metal/polymer

MBH - prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer

NPJ - prosthesis, knee patellofemorotibial, partial, semi-constrained, cemented, polymer/metal/polymer

HRY - prosthesis, knee, femorotibial, semi-constrained, cemented, metal/polymer

HSX - prosthesis, knee, femorotibial, non-constrained, cemented, metal/polymer

Legally Marketed Device to Which Substantial Equivalence is Claimed:

The primary predicate for this submission is K172326, Triathlon Total Knee System, Triathlon Partial Knee System, Restoris Multi-Compartmental Knee System.

The secondary predicates for this submission are K211303, Avon Patello-femoral Joint Prosthesis and K230952, Triathlon Pro Posterior Stabilized Femoral Component.

Triathlon Knee System

Femoral Components

Description	Previous Premarket Notifications
Triathlon CR Femoral Component	K040267, K141056, K172326, K201343
Triathlon TS Femoral Component	K070095, K141056, K172326, K201343
Triathlon PS Femoral Component	K042993, K141056 K172326, K201343
Triathlon® Posterior Stabilized Femoral Component with Peri-Apatite Left	K051380, K141056, K172326, K200782, K201343
Triathlon® Cruciate Retaining Femoral Component with Peri-Apatite Left	K051380, K141056, K172326, K200782, K201343
Triathlon® Pro Posterior Stabilized Femoral Cemented	K230952, K201343

Tibial baseplates and screws

Triathlon PRIMARY Tibial Baseplate Cemented	K062037, K141056, K172326, K201343
Triathlon Universal Tibial Baseplate	K053514, K141056, K172326, K201343
Triathlon Primary Baseplate Beaded with PA	K051380, K141056, K172326, K201343
TRIATHLON® TRITANIUM® Tibial Component (Impactor Pad Included)	K123486, K141056, K172326, K201343, K190402
Screw Fixation Baseplate with PA	K072575, K141056, K172326, K201343
Low Profile baseplate	K062037, K141056, K172326, K201343
Vitallium Screw	K072575, K141056, K172326

Tibial Inserts and All Poly Tibial Components

Triathlon CR Tibial Insert - N2Vac	K042883, K141056, K172326, K201343, K173849, K190402
Triathlon CR Tibial Insert - Gas Plasma	K051146, K141056, K172326, K201343
Triathlon CR Tibial Insert - X3 ETO	K172634, K173849, K190402
Triathlon CS Tibial Insert - N2Vac	K063423, K141056, K172326, K201343
Triathlon CS Tibial Insert - Gas Plasma	K063423, K141056, K172326, K201343
Triathlon CS Tibial Insert - X3 ETO	K172634, K173849, K190402
Triathlon PS Tibial Insert - N2Vac	K031729, K050539, K141056, K172326, K201343,
Triathlon PS Tibial Insert - Gas Plasma	K051146, K141056, K172326, K201343
Triathlon PS Tibial Insert - X3 ETO	K172634, K173849, K190402
Triathlon TS Tibial Insert- Gas Plasma	K070095, K072221, K141056, K172326, K201343
Triathlon TS Tibial Insert- X3 ETO	K172634, K173849
Triathlon PSR Tibial Insert - X3 ETO	K190402, K201343
TRIATHLON® ALL POLY Tibial Component- CS Cemented Use Only	K123166, K141056, K172326, K201343
Triathlon All Poly Tibial Component PS Cemented Use only	K123166, K141056, K172326, K201343

Femoral Augments/Femoral Cone Augments

Femoral Distal Augments - 5mm	K070095, K141056, K172326, K190991
Femoral Distal Augments - 10mm	K070095, K141056, K172326, K190991
Femoral Distal Augments - 15mm	K070095, K141056, K172326, K190991
Femoral Posterior Augments - 5mm	K070095, K141056, K172326
Femoral Posterior Augments - 10mm	K070095, K141056, K172326
Tritanium Lobed Femoral Cone	K143393, K172326
Tritanium Central Femoral Cone	K190991

Tibial Augments/Tibial Cone Augments

Tibial Half Block Augment 5mm	K053514, K141056, K172326
Tibial Half Block Augment 10mm	K053514, K141056, K172326
Tritanium Symmetric Tibial Augment	K143393, K172326
Tritanium Asymmetric Tibial Augment	K190991

Stems/Stem Extenders/Offset Adapters

50mm Long Cemented Stems	K053514, K141056, K172326
100mm Long Cemented Stems	K053514, K141056, K172326

150mm Long Cemented Stems	K053514, K141056, K172326
100mm Long Titanium Fluted Stems	K070095, K141056, K172326
150mm Long Titanium Fluted Stems	K070095, K141056, K172326
Offset Adapters	K070095, K141056, K172326
25mm Stem Extender	K070095, K141056, K172326

Peg

Triathlon Femoral Peg	K031729, K141056, K172326

Patellar Components

Metal Backed Patella with PA Coating	K061521, K141056, K172326
Triathlon X3 Gas Plasma All Poly Symmetric Patella	K051146, K051948, K052917, K141056, K172326, K210343
Triathlon X3 ETO All Poly Symmetric Patella	K172634, K173849
Triathlon N2Vac All Poly Symmetric Patella	K040267, K051948, K052917, K141056, K172326
Triathlon X3 Gas Plasma All Poly Asymmetric Patella	K051146, K141056, K172326
Triathlon X3 ETO All Poly Asymmetric Patella	K172634, K173849
Triathlon N2Vac All Poly Asymmetric Patella	K040267, K141056, K172326
Triathlon Tritanium Asymmetric Patella	K132624, K141056, K172326
Triathlon Tritanium Symmetric Patella	K132624, K141056, K172326

Triathlon Partial Knee System

Unicondylar Femoral Component - Cemented	K071881, K082567, K172326, K203099
Unicondylar Tibial Insert	K071881, K082567, K172326, K203099
Unicondylar Tibial Insert - ETO	K203099, K180612
Unicondylar Tibial Baseplate - Cemented	K071881, K082567, K172326, K203099

Avon Patello-femoral Joint Prosthesis

Avon Femoral Component	K041160, K051948, K052917, K211303
Avon Patella - UHMWPE	K041160, K051948, K052917, K211303

Restoris Multi-Compartmental Knee System

Femoral Component	K082172, K090763, K150307, K220930
Tibial Baseplate	K082172, K090763, K150307, K220930
Patella Resurfacing Round Dome	K082172, K090763, K150307, K220930
Tibial Onlay Inserts	K082172, K090763, K150307, K220930
MAKO X3 Uni Tibial Onlay Inserts	K180612

Device Description: All of the subject devices have been found substantially equivalent in previous 510(k)s. All the subject devices have been cleared for MR conditional labeling in previous 510(k)s. The purpose of this submission is to modify the MR conditional information in the instructions for use to update the parameters in which a patient who has the device can be safely scanned, per testing conducted accordance to updated FDA guidance. There have been no changes made to the devices requiring 510(k) clearance – only the MR conditional information in the instruction for use is being modified.

An additional contraindication is being added to the components of the Triathlon Total Knee System. This contraindication regarding material sensitivity to implant materials is being added.

Intended Use: In general, these devices are intended for use in primary or revision knee arthroplasty.

Indications:

Triathlon Knee System
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® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.
The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.
The Triathlon® All Polyethylene tibial components are indicated for cemented use only.
Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:
• Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:
• Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.

• Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:
• Severe degeneration or trauma requiring extensive resection and replacement
• Femoral and Tibial bone voids
• Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

Triathlon Pro Posterior Stabilized Femoral Components
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.
Additional Indications for Posterior Stabilized (PS) components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.
The Triathlon® Pro PS Femoral Components are intended for cemented use only.

Triathlon Tritanium Tibial Baseplate
Indications for Use:
General Total Knee Arthroplasty (TKR) Indications:
• Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid 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

Additional General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint

• Absent or non-functioning posterior cruciate ligament
• Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

Triathlon Low Profile Tibial Tray
Indications for Use:
The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon® femoral components and associated patellar components, and tibial bearing inserts in primary cemented total knee arthroplasty. The indications for the Triathlon® Low Profile Tibial Tray are outlined below:
Indications for Use:
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, 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.

Triathlon Metal Backed Patella
Indications for Use:
• Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed;
• Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
• Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Triathlon Partial Knee System
Indications for Use:
• Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
• Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
• As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
• Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are intended for implantation with bone cement.

Avon Patello-femoral Joint Prosthesis
The Avon Patello-femoral Joint Prostheses is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. These components are single use only and are intended for implantation with bone cement.

Restoris Multi-Compartmental Knee System
Restoris MCK is indicated for single or multi-compartmental knee replacement used in conjunction with RIO, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis, or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces.
The specific knee replacement configurations include:
• Medial unicondylar
• Lateral unicondylar
• Patellofemoral
• Medial bi-compartmental (medial unicondylar and patellofemoral)

Restoris Multi Compartmental Knee is for single use only and is intended for implantation with bone cement.

Summary of Technological Characteristics:

There have been no changes requiring 510(k) clearance to the technological characteristics of the Stryker Knee systems as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:

The Stryker Knee System devices were previously evaluated and cleared for conditional use in a Magnetic Resonance Environment through non-clinical testing as outlined in Attachment CH3.08 - Performance Testing.

New testing was performed to comprehensively assess the RF-related heating effects induced by the subject devices when implanted into bone, following the FDA guidance document, “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” dated May 20, 2021.

The labeling of the Stryker Knee System devices has been modified to provide the parameters under which a patient who has the device can be safely scanned.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Stryker Orthopaedics Knee System devices are substantially equivalent to the predicate device identified in this premarket notification.

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device.