



October 30, 2017

Stryker Orthopaedics  
Margaret Klippel  
Senior Regulatory Affairs Project Manager  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K172326

Trade/Device Name: Triathlon Total Knee System, Triathlon PKR System, Restoris MCK 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, MBH, HRY, KRR, HSX, NPJ

Dated: July 31, 2017

Received: August 1, 2017

Dear Ms. Klippel:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: 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.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



### Indications for Use

510(k) Number (if known):

Device Name: Triathlon Low Profile Tibial Tray

Indications for Use:

The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon<sup>®</sup> femoral components and associated patellar components, and tibial bearing inserts in primary cemented total knee arthroplasty. The indications for the Triathlon<sup>®</sup> 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Triathlon PKR 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)





### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Restoris MCK

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.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



## 510(k) Summary

**Sponsor** Stryker Orthopaedics  
325 Corporate Drive  
Mahwah, NJ 07430

**Contact Person** Margaret Klippel  
Senior Principal Regulatory Affairs Project Manager  
Stryker Orthopaedics  
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Mahwah, NJ 07430  
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**Date Prepared:** October 26, 2017

**Proprietary Name:** Triathlon Total Knee System  
Triathlon Partial Knee System  
Restoris MCK System

**Common Name:** Total/Partial Knee Joint Replacement

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

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

Knee joint femorotibial metal/polymer semi- constrained cemented prosthesis (888.3530)

Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (888.3540)

Knee joint femorotibial metal/polymer non-constrained cemented prosthesis (888.3520)

**Product Codes:** JWH, MBH, HRY, KRR, HSX, NPJ

**Legally Marketed Device to Which Substantial Equivalence is Claimed:** Triathlon Total Knee System components cleared via the following 510(k) submissions: K031729, K040267, K042883, K042993, K050539, K051146, K051380, K053514, K061521, K062037, K063423, K070095, K072221, K072575, K123166, K123486, K132624, K141056 and K143393; Triathlon PKR System cleared via K071881; Restoris MCK System cleared via K090763 and K150307.

**Device Description:**

The devices covered by this submission include femoral components, tibial baseplates, tibial inserts, all-polyethylene tibial components, patellar components, metal backed patellar components, tibial and femoral augments, stems, stem extenders and offset adaptors used in total knee arthroplasty procedures, as well as femoral components, tibial inserts, tibial baseplates, patellofemoral components and patellar components used in partial knee replacements. All devices have been previously determined substantially equivalent in prior 510(k) submissions and are commercially available. The Triathlon/Restoris Knee system components are manufactured from the following materials Cobalt Chromium Alloy, Titanium Alloy, Commercially Pure Titanium, Ultra-High Molecular Weight Polyethylene and Calcium Phosphate.

The purpose of this submission is to modify the labeling of the Triathlon Total Knee System, Triathlon PKR System, and Restoris MCK System to add MR Conditional labeling. Additionally, a revision to the contraindications for the Triathlon PKR System is being made.

**Indications:**

There are no changes to the previously cleared 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.

**Indications for Use for the Triathlon Tritanium Tibial Baseplate are:**

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.

**Indications for Use for the Triathlon Low Profile Tibial Tray are:**

The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon<sup>®</sup> 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.

**Indications for Use for the Triathlon Metal Backed Patella are:**

- 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.

**Indications for Use for the Triathlon PKR System are:**

- 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 unicompartamental knee prosthesis
- As an alternative to tibial osteotomy in patients with unicompartamental 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.

**Indications for Use for the Restoris MCK 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 to the technological characteristics of the subject knee system devices 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 following non-clinical laboratory testing was performed to determine substantial equivalence:

Non-clinical testing as outlined in the FDA guidance document “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff”, dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics partial/total knee passive implants in the MR environment. FDA guidance “Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Guidance for Industry and FDA Staff”, dated March 22, 2016 was also consulted for the heating evaluations performed. Testing was performed according to the standards listed below:

- Magnetically Induced Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment
- Magnetically Induced Torque – performed per ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment
- Image Artifact – performed per ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from passive Implants
- Heating by RF Fields per ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during MR Imaging

The labeling has been modified to include the MR conditional symbol, and to provide the parameters under which a patient who has the device can be safely scanned. Additionally, for certain devices, a contraindication was removed.

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

**Conclusion:** The Triathlon Knee System components, Triathlon PKR components and Restoris MCK components are substantially equivalent to the predicate devices identified in this premarket notification.