Howmedica Osteonics Corp aka Stryker Orthopaedics
Emily DiMambro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

June 7, 2018

Re: K180612
Trade/Device Name: Triathlon® PKR X3® Tibial Inserts, Mako X3® Uni Onlay Tibial Inserts
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, HRY, NPJ
Dated: February 28, 2018
Received: March 8, 2018

Dear Emily DiMambro:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180612

Device Name:

Mako X3® Uni Onlay Tibial Inserts

Indications for Use *(Describe)*

Mako X3® Uni Onlay Tibial Inserts are components of the RESTORIS Multicompartmental Knee (MCK) System that 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 Multicompartmental Knee (MCK) System 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180612

Device Name:

Triathlon® PKR X3® Tibial Inserts

Indications for Use *(Describe)*

Triathlon® PKR X3® Tibial Inserts are components of the Triathlon® PKR System that is indicated for:
• 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.

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510(k) Summary

Sponsor Howmedica Osteonics Corp aka Stryker Orthopaedics
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Date Prepared: February 28, 2018

Proprietary Name: Triathlon® PKR X3® Tibial Inserts and Mako X3® Uni Onlay Tibial Inserts

Common Name: Partial Knee Joint Replacement

Classification Name: 21 CFR 888.3520 - Knee joint femorotibial metal/ polymer non constrained cemented prosthesis

Product Codes: HSX, HRY, NPJ

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Triathlon PKR System X3 Tibial Inserts (K071881, K172326)
- Restoris Multicompartmental Knee (MCK) System X3 Tibial Inserts (K150307, K172326)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon X3 Tibial Inserts and Patellar Components (K172634)

Device Description: The subject Triathlon PKR X3® Tibial Inserts and Mako X3® Uni Onlay Tibial Inserts are identical in design to their currently marketed predicates. The subject inserts will use a different method of terminal sterilization of ethylene oxide per ISO 11135 and will be formed by consolidating GUR1020 resin via conventional methods which meet the specifications of ASTM F648. The device sterilization method is identical to that used for the reference Triathlon X3 Tibial Inserts and Patellar Components.

Intended Use:
The subject devices have the same intended use as those specified in the 510(k) clearances for the predicate devices listed.

Indications:

Device Name: **Triathlon® PKR X3® Tibial Inserts**

Indications for Use:
Triathlon® PKR X3® Tibial Inserts are components of the Triathlon® PKR System that is indicated for:

- 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.

Device Name: **Mako X3® Uni Onlay Tibial Inserts**

Indications for Use:

Mako X3® Uni Onlay Tibial Inserts are components of the RESTORIS™ Multi-compartmental Knee (MCK) System that 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™ Multicompartmental Knee (MCK) System is for single use only and is intended for implantation with bone cement.

Summary of Technological Characteristics: The subject components are identical in intended use, indications, design, and operational principles as the predicate devices. The subject devices are different from the predicate devices in their terminal sterilization method. The subject devices are terminally sterilized by Ethylene Oxide, whereas the predicate devices are sterilized using Gas Plasma. Consolidation of the X3® polyethylene material will be performed via conventional methods. The X3® UHMWPE continues to meet the same ASTM F648 specification. Both the subject and predicate Triathlon PKR X3® Tibial Inserts and Mako X3® Uni Onlay Tibial Inserts are labeled as MR-conditional according to the terminology specified in ASTM F2503-05. MR-conditional labeling for the predicate devices was cleared in K172326.

An identical change in sterilization for the Triathlon X3® Total Knee Tibial Insert and Patellar Components was cleared in K172634.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial equivalence:

1) Material Testing per ASTM F648, ASTM F2565, and FDA Guidance, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" (February 12, 2016).
2) Biocompatibility Testing per EN ISO 10993-1:2010 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" (June 16, 2016)
3) Ethylene Oxide Sterilization Validation per EN ISO 11135:2014
4) Static Shear Insert Baseplate Locking Mechanism Test
5) Posterior Edge Fatigue Test
6) Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an Endotoxin limit of <20 EU/Device
7) MR safety evaluation per ASTM F2052-2015, ASTM F2213-2011, ASTM F2119-2007, and ASTM F2182-2011

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

Conclusion: The subject Triathlon PKR X3® Tibial Inserts and Mako X3® Uni Onlay Tibial Inserts are substantially equivalent to the predicate devices identified in this premarket notification.

Device comparison showed that the proposed devices are substantially equivalent in intended use, materials, and performance characteristics to their respective predicate devices. The proposed modification does not affect safety or effectiveness.