October 27, 2020

Howmedica Osteonics Corp., aka Stryker Orthopaedics
Allison Byrne
Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K203099
Trade/Device Name: Triathlon PKR System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: October 12, 2020
Received: October 14, 2020

Dear Allison Byrne:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for Ting Song, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203099

Device Name
Triathlon PKR 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."

510(k) Summary

Sponsor	Howmedica Osteonics Corp aka Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Allison Byrne Regulatory Affairs Specialist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 (201) 831-5969
Alternate Contact	Margaret Klippel Chief Regulatory Affairs Speicalist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 (201) 831-5559
Date Prepared:	October 12th, 2020
Proprietary Name:	Triathlon PKR System
Common Name:	Partial Knee Joint Replacement
Classification Name:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis (21 CFR § 888.3520) Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3530) Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (21 CFR § 888.3540) Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3560)
Product Codes:	HSX; HRY; KRR; NPJ

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Triathlon® PKR System X3® Tibial Inserts, 5630-G-XXX-E (K180612)
- Triathlon® PKR System X3® Tibial Inserts, 5630-G-XXX (K172326)
- Triathlon® PKR Unicompartmental Femoral Component (K172326)
- Triathlon® PKR Unicompartmental Tibial Baseplate (K172326)

Subject devices Triathlon® PKR System X3® Tibial Inserts (5630-G-XXX), Triathlon® PKR Unicompartmental Femoral Component, and Triathlon® PKR Unicompartmental Tibial Baseplate were submitted previously in K082567 and K071881.

Device Description: The subject Triathlon® PKR System X3® Tibial Inserts (5630-G-XXX-E) are unchanged since the last premarket notification for the devices in K180612. The subject Triathlon® PKR System X3® Tibial Inserts (5630-G-XXX), Triathlon® PKR Unicompartmental Femoral Component, and Triathlon® PKR Unicompartmental Tibial Baseplate are unchanged since the last premarket notification for the devices in K172326.

The subject Triathlon® PKR System X3® Tibial Inserts (5630-G-XXX-E), Triathlon® PKR System X3® Tibial Inserts (5630-G-XXX), Triathlon® PKR Unicompartmental Femoral Component, and Triathlon® PKR Unicompartmental Tibial Baseplate are collectively referred to throughout this submission as the subject devices.

The purpose of this "Change Being Effected" premarket notification is to add a contraindication for the Triathlon® PKR X3® Tibial Inserts, Triathlon® PKR Unicompartmental Femoral Component, and Triathlon® PKR Unicompartmental Tibial Baseplate. Additionally, minor clarifications are being made to the labeling.

Intended Use:
The intended use of the subject devices is identical to the intended use specified in the 510(k) clearances for their respective predicate device. The subject devices are intended for use in Primary or Revision Partial Knee Arthroplasty.

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.

Summary of Technological Characteristics:
Neither the addition of the contraindication for which this "Change Being Effected" premarket notification is being submitted, nor the minor labeling clarifications, will change the technological characteristics of the subject devices.

Non-Clinical or Clinical Testing:
No additional testing was conducted for this submission, as the only changes being made are the addition of a contraindication and minor labeling clarifications. Testing performed in the previously cleared premarket notifications is applicable to this submission.

Conclusion:
The subject devices are substantially equivalent to their identified predicate device. The subject devices are identical in intended use, indications, design, technological characteristics and operational principles as described in the last premarket notification for the subject devices. The only changes made to the subject devices are the added contraindication and minor labeling clarifications.