June 4, 2021

Howmedica Osteonics Corp., dba Stryker Orthopaedics
Shraddha More
Staff Specialist, Regulatory Affairs
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K211303
Trade/Device Name: Avon Patello-femoral Joint Prosthesis
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: April 27, 2021
Received: April 29, 2021

Dear Shraddha More:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211303

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.

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510(k) Summary

Sponsor	Howmedica Osteonics Corp. dba Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Shraddha More Staff Specialist, Regulatory Affairs Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5804 Email: shraddha.more@stryker.com
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Date Prepared:	April 26, 2021
Proprietary Name:	Avon Patello-femoral Joint Prosthesis
Common Name:	Patello-femoral Joint Prosthesis
Classification Name:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (21 CFR § 888.3540)
Product Codes:	KRR

Legally Marketed Devices to which Substantial Equivalence is Claimed:

Primary Predicate Device:

- Avon Patello-femoral Joint Prosthesis (K051948)

Reference Devices:

- Avon Extra-small Patello-femoral Replacement (K041160)
- Avon Patellar Component (K020841)
- Avon Patello-femoral Joint Prosthesis (K010100)

Device Description:

This submission covers the Avon femoral and patellar components of the Avon Patello-femoral Joint Prosthesis. The femoral components are manufactured from Cobalt Chrome (CoCr) and the patellar components are manufactured from Ultra-high Molecular Weight Polyethylene (UHMWPE) materials.

The purpose of this submission is to add Magnetic Resonance (MR) Conditional labeling to the labeling of the Avon femoral and patellar components of the Avon Patello-femoral Joint Prosthesis. Additionally, minor labeling and packaging updates, as detailed in the respective sections, are also included in this submission.

Indications for Use:

The indications for the subject components are as follows:

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.

Summary of Technological Characteristics:

There have been no changes to the technological characteristics of the subject Avon femoral and patellar components of the Avon Patello-femoral Joint Prosthesis as a result of the revision to the labeling. The subject components have the same design and are manufactured from the same materials as the predicate components.

Non-Clinical Testing:

The subject Avon femoral and patellar components of the Avon Patello-femoral Joint Prosthesis were evaulated as per the following standards:

- Magnetically Induced Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- Magnetically Induced Torque – performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance 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 F2182-19, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

It was concluded that the subject Avon femoral and patellar components of the Avon Patello-femoral Joint Prosthesis do not present a new worst case with respect to magnetically induced displacement force, torque, MR image artifacts, and RF-induced heating. Therefore, the Avon components are qualified to be "MR Conditional" for MR-induced displacement, torque and image artifacts, and RF-induced heating.

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 in the MR environment.

Clinical Testing:

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

Conclusion:

Based upon a comparison of the intended use, materials, summary of technological characteristics, and preclinical evaluation, the subject components are substantially equivalent to the respective predicate components identified in this premarket notification.