March 11, 2024

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Meenakshi Verma
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K233724
Trade/Device Name: 28mm/38D MDM X3 Insert for MDM Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: November 21, 2023
Received: November 21, 2023

Dear Meenakshi Verma:

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.

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
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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.

Submission Number *(if known)*

K233724

Device Name

28mm/38D MDM X3 Insert for MDM Liner

Indications for Use *(Describe)*

The indications for use for total hip arthroplasty include:
1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and,
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6. Dislocation risks

MDM Liners are intended for cementless 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.

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510(k) Summary

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Date Prepared: 1-March-2024

Proprietary Name: 28mm/38D MDM X3 Insert for MDM Liner

Common Name: Total Hip Joint Replacement

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)

Product Codes: LPH, LZO, MEH

Primary Predicate Device to Which Substantial Equivalence is Claimed:

- Trident X3 Acetabular Inserts, ADM and MDM X3 Acetabular Inserts, Accolade II Hip System (K182468)

Additional Predicate Devices Used to Support Substantial Equivalence:

- G7 Dual Mobility System, Active Articulation System (K161190)

Reference Device Used to Support Substantial Equivalence :

- Exeter X3 RimFit Cup (K213701)

Reason for 510(k) Submission:
The purpose of this submission is to introduce a line extension to the MDM X3 Modular Dual Mobility Acetabular System, specifically a 28mm/38D MDM X3 Insert for MDM Liner.

Device Description:
The subject device is an MDM X3 Insert with an inner diameter of 28mm and outer diameter of 38mm. It is a sterile, single-use device that will articulate within the inner surface of the highly polished cobalt chrome MDM Liner and will be compatible with 28mm Howmedica Osteonics femoral heads. The subject device is compatible with the same liners, cups, and femoral stems as the previously cleared Stryker dual mobility hip systems. The polyethylene MDM X3 Insert and femoral head combine to create the dual mobility bearing. The subject MDM X3 Insert is manufactured from sequentially crosslinked and annealed polyethylene, known as X3. The resin used is Type 1 (GUR 1020) which meets the requirements of ASTM F648.

Intended Use:
The subject device has the same intended use as that specified in the 510(k) clearance for the predicate devices.

Indications:
The indications for use for total hip arthroplasty include:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks

MDM Liners are intended for cementless use only.

Summary of Technological Characteristics:
The subject X3 acetabular insert has the same intended use, indications for use, material and operational principles as those of the predicate devices. The design of the subject device is similar to its predicate devices. The predicate MDM X3 Inserts have an inner diameter of 22.2mm and outer diameter of 36mm and 38mm. Restoration ADM X3 Inserts and Restoration ADM/MDM X3 Inserts have an inner diameter of 28mm and outer diameter ranging from 40mm to 58mm in 2mm increments. The predicate acetabular inserts are compatible with 22.2mm or 28mm Howmedica Osteonics femoral heads, respectively. The subject MDM X3 Insert has an inner diameter of 28mm and outer diameter of 38mm. It will articulate within the inner surface of the highly polished cobalt chrome MDM Liner and will be compatible with 28mm Howmedica Osteonics femoral heads.

The subject device 28mm/38D MDM X3 Insert is thinner than the Stryker predicates ADM and MDM X3 acetabular inserts but similar in size/dimensions as compared to the additional predicate 28/38 Dual Mobility heads (K161190).

Non-Clinical Testing:
The following non-clinical laboratory testing was performed, or engineering analysis was conducted to determine substantial equivalence:

- Material testing per FDA's guidance titled, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices," issued April- 26-2019.
- Biocompatibility evaluation per ISO 10993-1:2018, ISO 10993-7:2008 and FDA's guidance titled, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," issued September 4, 2020.
- Ethylene oxide sterilization validation per ISO 11135:2014
- Bacterial endotoxin testing (BET)
- Axial pull out resistance
- Cam-out strength
- Wear testing
- Axial Fatigue
- Rim Fatigue
- Range of Motion
- Dislocation Resistance
- Impingement FEA
- MRI Safety Testing

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

Conclusion:
Based upon a comparison of the intended use, indications for use, design, materials, technical and performance characteristics, and operational principles, the 28mm/38D MDM X3 Insert for MDM Liner is substantially equivalent to the predicate devices identified in this premarket notification.