May 13, 2019

Howmedica Osteonics Corp aka Stryker Orthopaedics
Krutanjali Shah
Manager, Regulatory Affairs
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K182468
Trade/Device Name: Trident X3 Acetabular Inserts, ADM and MDM X3 Acetabular Inserts, Accolade II Hip System
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, JDI, MEH, LZO, KWL, KWZ, LWJ, KWY
Dated: September 5, 2018
Received: September 10, 2018

Dear Krutanjali Shah:

This letter corrects our substantially equivalent letter of March 19, 2019.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2019.05.13 22:59:04 -04'00'

For: CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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)*
K182468

Device Name
Trident® X3® UHMWPE Acetabular Inserts,
Restoration ADM® and MDM® X3® UHMWPE Acetabular Inserts

Indications for Use *(Describe)*

Trident Acetabular Component System
Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Restoration ADM Acetabular Cup and MDM Liner Systems
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

RESTORATION ADM HA Cups and 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.

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)*
K182468

Device Name
Accolade II Hip System

Indications for Use *(Describe)*
Accolade II Hip System
The indications for use of the total hip replacement prostheses 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. nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
Additional indication specific to use of ACCOLADE II Femoral Stems with compatible Howmedica Osteonics

Constrained Liners:
1. When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.
ACCOLADE II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

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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Section 5: 510(k) Summary

510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Krutanjali Shah Manager, Regulatory Affairs Howmedica Osteonics Corp 325 Corporate Drive, Mahwah, NJ 07430 Phone: (201) 831-5665
Date Prepared:	March 15, 2019
Proprietary Name:	Trident® X3® UHMWPE Acetabular Inserts, Restoration ADM® and MDM® X3® UHMWPE Acetabular Inserts, Accolade® II Hip System
Common Name:	Total Hip Joint Replacement
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360) Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390) Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
Product Codes:	LPH, JDI, MEH, LZO, KWL, KWY, KWZ, LWJ

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Trident® X3® Acetabular Inserts (K033716, K061434, K062419, K153345)
- Restoration ADM® and MDM® X3® Acetabular Inserts (K093644, K103233, K112556, K153345)
- Accolade® II Hip System (K103479, K120578, K153345)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components (K172634)
- Trident® N2Vac UHMWPE Acetabular Inserts (K983502, K983382)
- Restoration ADM® Duration® UHMWPE Acetabular Inserts (K072020)

Device Description: The subject X3 UHMWPE Acetabular Inserts for the Trident, Restoration ADM and MDM Liner systems are a modified version of their respective predicate devices. The subject device designs are identical to their respective predicates, but the subject devices will have a different method of terminal sterilization (ethylene oxide) and will be formed by consolidating Type 1 (GUR1020) resin via conventional methods which meet the specifications of ASTM F648.

The subject Accolade II Hip System is identical to the predicate Accolade II Hip System, with the exception that it has additional compatibility with new instrumentation which utilizes an addendum to the current surgical protocol.

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

Indications:
Trident Acetabular Component System
Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Restoration ADM Acetabular Cup and MDM Liner Systems
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

RESTORATION ADM HA Cups and MDM Liners are intended for cementless use only.

Accolade II Hip System
The indications for use of the total hip replacement prostheses 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. nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head

involvement that are unmanageable using other techniques.

Additional indication specific to use of ACCOLADE II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:
1. When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.
ACCOLADE II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Summary of Technological Characteristics: The subject X3 UHMWPE Acetabular Inserts are identical in intended use, indications, design, and operational principles to the predicate devices. The subject devices differ from the predicate devices with regard to their terminal sterilization method: The subject devices are terminally sterilized by Ethylene Oxide, whereas the predicate devices are sterilized using Gas Plasma. Consolidation of X3 polyethylene is performed using conventional methods. The X3 UHMWPE material continues to meet the same ASTM F648 specification.

The subject Accolade II Hip System is identical in intended use, indications, design, and operational principles to the predicate Accolade II Hip System. The subject device differs from the predicate device with regard to additional compatibility with new instruments which utilizes an updated surgical technique.

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

1) Material testing per ASTM F648, ASTM F2565, and Draft FDA Guidance, “Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” (February 12, 2016).
2) Biocompatibility Evaluation per ISO 10993-1:2009, ISO 10993-7:2008, 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 ISO 11135:2014
4) Bacterial endotoxin testing (BET)
5) Trident axial push out testing
6) Trident rim loading fatigue testing
7) Trident wear testing based on ISO/DIS 14242-1
8) MDM Liner cam-out testing

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

Conclusion: The subject X3 UHMWPE Acetabular Inserts and Accolade II Hip System are substantially equivalent to their respective predicate devices identified in this premarket notification.

Device comparison showed that the proposed devices are substantially equivalent in intended use, technological characteristics and principles of operation as compared to the predicate devices. The proposed modifications do not affect safety or effectiveness.