March 9, 2022

Howmedica Osteonics Corp., dba Stryker Orthopaedics
Lin Song
Senior Manager, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K220376
Trade/Device Name: Acetabular Dome Hole Plug
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, KWZ, LZO, MEH, JDI
Dated: February 8, 2022
Received: February 10, 2022

Dear Lin Song:

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,

Limin Sun, Ph.D.
Acting 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)*
K220376

Device Name
Acetabular Dome Hole Plug

Indications for Use *(Describe)*

Indications:
In cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous.
Indications for use when used with the Trident II Acetabular Shells.
• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic 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.
When used with MDM Liners
• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
• Dislocation risks
When used with Constrained Liners
• The Trident® Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Trident II Acetabular Shells are indicated 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.

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510(k) Summary

Sponsor: Howmedica Osteonics Corp dba Stryker Orthopaedics
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Mahwah, NJ 07430

Contact Person: Lin Song
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Phone: (201) 831-6617

Date Prepared: February 8, 2022

Proprietary Name: Acetabular Dome Hole Plug

Common Name: Acetabular Implant Device

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 non-Porous uncemented (21 CFR §888.3353)

Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310)

Product Codes: LPH, KWZ, LZO, MEH, JDI

Legally Marketed Predicate Device to Which Substantial Equivalence is Claimed:

- Acetabular Dome Hole Plugs (K942809, K191358)

Legally Marketed Reference Devices Supporting Substantial Equivalence:

- Stryker Orthopaedics Total Hip Systems Labeling Update (K153345)

Device Description

The Acetabular Dome Hole Plug, originally cleared via K942809, is an optional device used to seal acetabular shells. The Acetabular Dome Hole Plug has a threaded disc profile that can be screwed into the threaded dome hole of an acetabular shell sealing the device. Once assembled, the inferior face of the Acetabular Dome Hole Plug will be flush with the internal surface of the acetabular shell.

This Special 510(k) submission proposes labeling modifications to the package insert that was previously cleared in K191358 for the Acetabular Dome Hole Plug for use with the compatible Stryker Acetabular Shells. Specifically, the proposed labeling change is to remove the contraindication related to obesity and replace it with a warning statement concerning patient weight.

There is no change to the design (e.g., materials, dimensions, etc.) of the Acetabular Dome Hole Plug and no change to the direction for use of the device. The intended use, packaging, and sterilization of the Acetabular Dome Hole Plug device also remain unchanged.

Indications for Use

Indications

- In cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous.

Indications for use when used with the Trident II Acetabular Shells.

• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic 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.

When used with MDM Liners

• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

• Dislocation risks

When used with Constrained Liners

• The Trident® Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Trident II Acetabular Shells are indicated for cementless use only.

Summary of Technological Characteristics

There are no changes to the technological characteristics of the subject Acetabular Dome Hole Plug due to the revision to the labeling. The Acetabular Dome Hole Plug has identical design and is manufactured from the same materials as the predicate device. The way the Acetabular Dome Hole Plug interacts with the compatible Stryker Acetabular Shells remains unchanged.

Non-Clinical Testing

Performance testing was not required in support of the labeling modifications to remove the obesity contraindication from, and add warning language concerning patient weight to, the package insert. The compatible acetabular shells do not contraindicate obesity. Since Acetabular Dome Hole Plug is an accessory to the shell, it is not practical to have a contraindication for an accessory device that is in conflict with the parent device.

Based on the definitions for “contraindications” and “warnings” from the FDA’s Device Labeling Guidance #G91-1 (Blue Book Memo), obesity should not be considered a

contraindication to total hip arthroplasty, but rather a warning that should be adequately assessed by the surgeon and clearly communicated to the patient.

The revisions to the Acetabular Dome Hole Plug package insert do not present any new issues of safety or effectiveness.

Clinical Testing

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

Conclusion

The subject Acetabular Dome Hole Plug is substantially equivalent to the predicate Acetabular Dome Hole Plug cleared in K942809 and K191358. Device comparison demonstrated that the subject Acetabular Dome Hole Plug is identical in design, materials, operational principles, and performance characteristics to its predicate. The proposed labeling modifications do not affect the safety or effectiveness of the subject device.