May 20, 2022

Howmedica Osteonics, dba Stryker Orthopaedics
Margaret Klippel
Chief Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K220838
Trade/Device Name: Artisan Bone Plug, Universal Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: LZN, JDI
Dated: March 18, 2022
Received: March 22, 2022

Dear Margaret Klippel:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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)*
K220838

Device Name
Artisan Bone Plug

Indications for Use *(Describe)*
These bone plugs are intended to be placed in the femoral canal prior to the introduction of bone cement in a cemented hip procedure. The plug is placed distally to the femoral stem to help allow cement pressurization and to help prevent cement migration further down the femoral canal.

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

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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)*

K220838

Device Name

Universal Cement Restrictor

Indications for Use *(Describe)*

For cement spacers, mid-shaft restrictors and Cement Plugs:

• In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

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)

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510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Margaret Klippel
Chief Specialist, Regulatory Affairs
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430
Telephone: 201-831-5559

Date Prepared: May 20, 2022

Proprietary Name: Labeling Update for Artisan Bone Plug and Universal Cement Restrictor

Common Name: Artificial Hip Replacement Components

Regulatory Class: Class II

Regulation: Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350

Surgical Mesh 21 CFR §878.3300

Product Codes: LZN – cement obturator

JDI – Prosthesis, hip, semi-constrained, metal/polymer, cemented

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Artisan Bone Plug – K951860
Universal Cement Restrictor – K924323

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:
Universal Distal Spacer – K914406, K153345

Device Description:
The Artisan Bone Plug and Universal Cement Restrictor are commercially available devices that have been determined substantially equivalent in previous 510(k) premarket notifications. The purpose of this submission is to modify the labeling of these devices to add MR Conditional labeling and make other minor labeling updates.

Indication for Use:

There are no changes to the previously cleared indications for use. The indications for the subject components are as follows.

Artisan Bone Plug:
These bone plugs are intended to be placed in the femoral canal prior to the introduction of bone cement in a cemented hip procedure. The plug is placed distally to the femoral stem to help allow cement pressurization and to help prevent cement migration further down the femoral canal.

Universal Cement Restrictor:
For cement spacers, mid-shaft restrictors and Cement Plugs:

- In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

Summary of Technological Characteristics:
There have been no changes to the technological characteristics of the subject devices as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:

In previous premarket notification K153345 non-clinical testing was presented to characterize the compatibility of Stryker Orthopaedics Hip System devices in the MR environment. Testing was performed according to the standards listed below:

- Magnetically Inducted Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment

- Magnetically Induced Torque – performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR 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 near Passive Implants during MR Imaging

An engineering analysis was conducted to determine if the Artisan Bone Plug and Universal Cement Restrictors pose a new worst case when compared to the devices previously tested in K153345. The results of this analysis indicated that the subject devices do not create a new worst case.

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.

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2019 was used for pyrogenicity testing to achieve an endotoxin limit of < 20EU/Device.

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

Conclusion: The subject Artisan Bone Plug and Universal Cement Restrictor components are substantially equivalent to the predicate devices identified in this premarket notification.