February 6, 2025

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Julia Bally
Regulatory Affairs Senior Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K243784
Trade/Device Name: Stryker Orthopaedics Hip Devices Labeling Update
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, JDI, MEH, KWZ, KWL, JDG, LZN, LWJ, KWY, MAY, MBL
Dated: December 9, 2024
Received: December 9, 2024

Dear Julia Bally:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243784

Device Name
Stryker Orthopaedics Hip Devices Labeling Update

Indications for Use *(Describe)*

Indications for Restoration Modular Hip System

- 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,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- The RESTORATION Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

Indications for Accolade C, Accolade HFx, SYSTEM 12 CROSSFIRE, ACCOLADE DISTAL SPACER, CITATION TMZF, PCA Duration Insert, PCA Femoral Head

- 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,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

Indications for Accolade II Stems

The indications for use of the total hip replacement prostheses 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,
- nonunions, femoral neck 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

- 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 intraoperative instability. ACCOLADE II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Indications for OMNIFIT SERIES Acetbular Inserts, Omnifit Crossfire10 Deg Inserts, Crossfire Eccentric Inserts, Omnifit Crossfire Inserts, Trident Crossfire Inserts, Trident X3 Inserts, Trident X3 Eccentric Inserts

- 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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Indications for ALL POLY CONSTRAINED INSERT, TRIDENT 0 DEG CONSTRAINED INSERT, TRIDENT CONSTRAINED INSERT

A Constrained Acetabular Insert is indicated for use as a component of a total hip prosthesis 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.

Indications for UHR Bipolar
• Femoral head/neck fractures or non-unions.
• Aseptic necrosis of the femoral head.
• Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
Other Considerations:
• Pathological conditions or age considerations which indicate a more conservative acetabular
procedure and an avoidance of the use of bone cement in the acetabulum.
• Salvage of failed total hip arthroplasty

Indications for 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.

Indications for C-Taper Alumina Ceramic Heads, V40 Taper Alumina Ceramic Heads,Ceramic V40™ Femoral Head
• 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

Indications for BIOLOX Delta Ceramic Heads, C-Taper to Universal Taper Adapter Sleeve, Universal V40™ Taper Adapter Sleeve
For Use as a Total Hip Replacement:
• Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
• Revision of previous cup arthroplasty or other procedures
• 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 in the acetabulum.

For Use as a Bipolar Hip Replacement
• Femoral head/neck fractures or non-unions.
• Aseptic necrosis of the femoral head.

• Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
• Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
• Salvage of failed total hip arthroplasty

Indications for ADM/MDM X3 Inserts, MDM Acetabular Inserts, MDM Acetabular Liners
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

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Julia Bally
Regulatory Affairs Senior Specalist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
201-831-6265
Julia.Bally@stryker.com

Alternate Contact Gregg Ritter
Principal Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430
Gregg.Ritter@stryker.com

Date Prepared: 04-February-2025

Proprietary Name: Stryker Orthopaedics Hip Devices Labeling Update

Common Name: Artificial Hip Replacement Components –Acetabular and Femoral

Classification Name:

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358
Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR §888.3310
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353
Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360
Surgical Mesh 21 CFR §878.3300
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR §888.3390

Product Codes: LPH, LZO, JDI, MEH, KWZ, KWL, JDG, LZN, LWJ, KWY, MAY, MBL

Primary Predicate Device to Which Substantial Equivalence is Claimed:
Submission Number: K121308
Device Name: Hip Systems
Product Codes: LPH, JDI, KWY, KWZ, LWJ, LZO, MAY, MBL, MEH

Additional Predicate Device Used to Support Substantial Equivalence:

K233498: Stryker Orthopaedics Hip Systems Labeling Update
K974685: OSTEONICS POLYETHYLENE ACETABULAR COMPONENTS
K900438: MC2P ACETABULAR COMPONENT

Reason for 510(k) Submission:

The purpose of this "Change Being Effected" submission is to add a contraindication to the labeling of the subject Stryker Orthopaedics Hip Devices.

Device Description:
The devices included in this submission are femoral stems, femoral heads, acetabular inserts, distal spacers, and bone plugs, used in hip arthroplasty procedures. All devices have been previously deemed substantially equivalent in prior premarket submissions and are commercially available.

Intended Use: In general, these devices are intended for use in primary or revision hip arthroplasty.

Indications:
Indications for Restoration Modular Hip System:

- 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,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- The RESTORATION Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

Indications for Accolade C, Accolade HFx, SYSTEM 12 CROSSFIRE, ACCOLADE DISTAL SPACER, CITATION TMZF, PCA Duration Insert, PCA Femoral Head

- 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,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

Indications for Accolade II Stems

The indications for use of the total hip replacement prostheses 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,
- nonunions, femoral neck 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:

- 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 intraoperative instability.

ACCOLADE II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Indications for OMNIFIT SERIES Acetbular Inserts, Omnifit Crossfire 10 Deg Inserts, Crossfire Eccentric Inserts, Omnifit Crossfire Inserts, Trident Crossfire Inserts, Trident X3 Inserts, Trident X3 Eccentric Inserts:

- 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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Indications for ALL POLY CONSTRAINED INSERT, TRIDENT 0 DEG CONSTRAINED INSERT, TRIDENT CONSTRAINED INSERT

A Constrained Acetabular Insert is indicated for use as a component of a total hip prosthesis 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.

Indications for UHR Bipolar
• Femoral head/neck fractures or non-unions.
• Aseptic necrosis of the femoral head.
• Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
Other Considerations:
• Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
• Salvage of failed total hip arthroplasty

Indications for 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.

Indications for C-Taper Alumina Ceramic Heads, V40 Taper Alumina Ceramic Heads,Ceramic V40™ Femoral Head
• 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

Indications for BIOLOX Delta Ceramic Heads, C-Taper to Universal Taper Adapter Sleeve, Universal V40™ Taper Adapter Sleeve
For Use as a Total Hip Replacement:
• Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
• Revision of previous cup arthroplasty or other procedures
• 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 in the acetabulum.

For Use as a Bipolar Hip Replacement
• Femoral head/neck fractures or non-unions.

• Aseptic necrosis of the femoral head.
• Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
• Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
• Salvage of failed total hip arthroplasty

Indications for ADM/MDM X3 Inserts, MDM Acetabular Inserts, MDM Acetabular Liners
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.

Summary of Technological Characteristics:

Technological characteristics of the subject devices are identical to those of the predicate devices identified in this submission. The labeling updates in this submission have no impact on the technological characteristics of the subject and predicate devices.

Non-Clinical Testing:

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

Clinical Testing:

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

Conclusion:
Based upon a comparison of the intended use, indications for use, design, materials, sterilization, technological characteristics, and operational principles, the subject devices are substantially equivalent to the predicate devices identified in this premarket notification.