April 12, 2024

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

Re: K240418
Trade/Device Name: Stryker Orthopaedics Hip Systems Labeling Update
Regulation Number: 21 CFR 888.3050
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, JDQ, HRS, LRN, LYT, LPH, JDG, KWY, LZO
Dated: February 12, 2024
Received: February 13, 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.

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

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)*

K240418

Device Name

Stryker Orthopaedics Hip Systems Labeling Update

Indications for Use *(Describe)*

DALL-MILES Cable System

The DALL-Miles System is indicated for reattachment of the trochanter in any hip procedure using the trochanteric osteotomy (total or partial) approach.

The DALL-MILES Mini Cleat is indicated for vertical reattachment or reinforcement of the trochanter in any situation where the surgeon feels that the trochanter is at risk for detachment.

The Mini Cleat is intended for use with the DALL-MILES System for trochanteric reattachment only.

The DALL-MILES Cables and Cable Sleeves are indicated for trochanteric reattachment and trauma surgery of the hip; to stabilize bone graft material; and for supplementary cerclage fixation with plates and screws for fracture fixation.

The DALL-MILES Trochanteric Grips and Grip Plates are indicated for use in the fixation of the greater trochanter due to trochanteric fracture or osteotomy with intramedullary fixation as the primary device.

The DALL-MILES Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

Femoral Heads

The indications for use for total hip and hemi 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.

Femoral Mesh

The indications for use for total hip and hemi 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.

Surgical Mesh. Surgical Mesh is intended to be used to reinforce bone or tissue in any situation where additional strengthening and support is required due to poor bone/tissue quality.

Intramedullary Plug, Centralizer

The indications for use of 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,

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

The EXETER Centralizer is intended to be used to centralize the femoral stem within the intramedullary canal and is intended to be used with bone cement.

The EXETER 2.5mm Intramedullary Bone Plug is intended to be used to restrict the migration of bone cement down the femoral canal and permit cement pressurization during total hip arthroplasty and is intended to be used with bone cement.

Exeter X3 RimFit Cups

The indications for use for total hip arthroplasty include:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.

2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.

3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

4. Where bone stock is of poor quality or inadequate for other reconstructive techniques, such as cementless fixation, as indicated by deficiencies of the acetabulum.

The Exeter X3 RimFit Cup is intended for cemented use only.

Femoral Stems

The indications for use for total hip and hemi 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.

The Exeter V40 Femoral Stem is intended for use in total or hemi hip replacement. It is intended for cemented 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
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Date Prepared: 12- February-2024

Proprietary Name: Stryker Orthopaedics Hip Systems Labeling Update

Common Name: Artificial Hip Replacement Components –Acetabular and Femoral

Classification Name:

888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis,
888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis,
888.3010 - Bone fixation cerclage,
888.3030 - Single/multiple component metallic bone fixation appliances and accessories,
888.3360 -Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis,
888.3390 - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis,
888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Product Codes: JDI, JDQ, HRS, LRN, LYT, LPH, JDG, KWY, LZO

Primary Predicate Device to Which Substantial Equivalence is Claimed:

- K213701: Exeter® X3® RimFit® Cup

Additional Predicate Device Used to Support Substantial Equivalence:

- K233498: Stryker Orthopaedics Hip Systems Labeling Update
- K202016: Dall-Miles® Cable System
- K121308: HIP SYSTEMS
- K193429: Exeter V40 Femoral Stem, Exeter X3 RimFit Cup

Reason for 510(k) Submission:

The purpose of this "Change Being Effected" bundled submission is to add a contraindication to the labeling of the subject Stryker Orthopaedics Hip Systems Labeling Update devices.

Device Description:

The devices covered by this bundled submission are Stryker Total Hip Systems which include Dall-Miles cable system components, femoral heads, femoral mesh, Intramedullary Plug, Centralizer, acetabular cups, and femoral stems. All devices are commercially available and have been cleared in prior 510(k) submissions.

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

Indications:

DALL-MILES Cable System

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The DALL-MILES Mini Cleat is indicated for vertical reattachment or reinforcement of the trochanter in any situation where the surgeon feels that the trochanter is at risk for detachment. The Mini Cleat is intended for use with the DALL-MILES System for trochanteric reattachment only.
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The DALL-MILES Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

Femoral Heads
The indications for use for total hip and hemi 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.

Femoral Mesh

The indications for use for total hip and hemi 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,
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Surgical Mesh. Surgical Mesh is intended to be used to reinforce bone or tissue in any situation where additional strengthening and support is required due to poor bone/tissue quality.

Intramedullary Plug, Centralizer

The indications for use of total hip replacement prostheses include:
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• 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.

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Exeter X3 RimFit Cups
The indications for use for total hip arthroplasty include:
1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Where bone stock is of poor quality or inadequate for other reconstructive techniques, such as cementless fixation, as indicated by deficiencies of the acetabulum.

The Exeter X3 RimFit Cup is intended for cemented use only.

Femoral Stems
The indications for use for total hip and hemi 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.

The Exeter V40 Femoral Stem is intended for use in total or hemi hip replacement. It is intended for cemented use only.

Summary of Technological Characteristics:

The technological characteristics of the subject devices are identical to those of the 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 method, technical and performance characteristics, and operational principles, the subject devices are substantially equivalent to the predicate devices identified in this premarket notification.