December 21, 2023,

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Julia Bally
Official Correspondent
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K233498
Trade/Device Name: Stryker Orthopaedics Hip Systems 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, KWZ, LZO, MEH, JDI, LWJ, KWL, JDG, KWY, MAY, MBL, HWC, JDQ, HRS, LRN, LYT, LZN
Dated: October 30, 2023
Received: October 31, 2023

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,

Christopher Ferreira -S

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233498

Device Name
Stryker Orthopaedics Hip Systems Labeling Update

Indications for Use *(Describe)*

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.

Universal Cement Restrictor, OmniFit Distal Cement Spacer
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.

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.

Trident® II Acetabular System (Trident II Cups (Clusterhole HA, PLS Clusterhold HA, Tritanium Clusterhole, Tritanium Multihole, Tritanium Solidback), 6.5mm Low Profile Hex Screw, Hex Dome Hole Plug
• 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 Liner:
• 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.

Restoration® Modular Hip System
The Restoration® Modular Hip System is indicated for use in:
• Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis
• Correction of functional deformity;
• Revisions procedure 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

Additional indications specific to the Restoration Modular Hip System
The Restoration® Modular Hip System is intended to be used 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.

Accolade II Femoral Stems, Anato Femoral Stem, Secur-Fit Advanced
The indications for use for total hip arthroplasty with stems 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 fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Femoral Stem 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 intra-operative instability.
The Stems are intended for cementless use only and are intended for total and hemiarthroplasty.

TRIDENT AND TRITANIUM® ACETABULAR COMPONENTS
• 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.

The HOWMEDICA OSTEONICS TRIDENT and TRITANIUM Acetabular Shells are intended for cementless use only. Dome hole plug is indicated for cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous

Acetabular Dome Hole Plug
The Dome Hole Plug is an optional device which is available to seal the Howmedica Osteonics Acetabular Shell components during cemented or cementless applications of the acetabular cup. The Howmedica Osteonics Done Hole Plug is threaded into the dome hole of the shell.
Indications
• In cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous.

DALL-MILES® SYSTEMS

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.

Exeter® V40™ Hip System (includes Orthinox V40 Femoral heads)
The Exeter® V40™ Femoral Hip System is indicated for:
• 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® V40™ Femoral Stem Hip System is intended for use in total or hemi hip replacement. It is intended for cemented use only.

Exeter Centralizer, EXETER Intramedullary Plug
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 Centralizer is intended to be used to centralize the femoral stem within the intramedullary canal. The Exeter Centralizer is intended to be used with bone cement.

The Exeter 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. The Exeter Intramedullary Bone Plug 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.

Restoration GAP II Acetabular Shell
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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.
Segmental and/or cavitary acetabular defects which make it difficult to restore normal hip biomechanics or to reconstitute the normal structural continuity and integrity of the acetabulum, using standard total hip replacement acetabular components and procedures.

Gap Screws, Torx Screws, and Osteolock Bone Screws
HOWMEDICA OSTEONICS Torx Cancellous Bone Screws are intended for supplemental fixation of associated HOWMEDICA OSTEONICS cementless Acetabular Shells.
• HOWMEDICA OSTEONICS RESTORATION GAP Plate Screws are intended for fixation of the dome and iliac plates of the associated HOWMEDICA OSTEONICS RESTORATION GAP Acetabular Shell, TRIDENT TRITANIUM Hemispherical Multihole Acetabular Shells, restoration Acetabular Augments, and Restoration Anatomic shells.

Insignia Hip Stem
Hip Arthroplasty Indications:
• Painful, disabling joint disease of the hip resulting from: noninflammatory degenerative joint disease (including osteoarthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
• Revision of previous unsuccessful femoral head replacement, hip arthroplasty or other procedure.
• Correction of functional deformity
• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of lnsignia Hip 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 intra-operative instability.

Additional indication specific to use of lnsignia Hip Stems with compatible ADM and MDM Acetabular Components:
• When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks

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

Omnifit HFX Femoral Stems
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.
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.

• Femoral neck fractures.
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 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.
• Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

Omnifit EON Cemented Femoral Stems
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.
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.
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 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.

Indications for use as a Total Hip Replacement 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.

Restoration Anatomic Shell
• 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.

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 Liner:
• 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 Restoration® Anatomic Shell is indicated for cementless use only.

Trident Constrained Acetabular Insert/ Constrained Acetabular Insert
The Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Trident X3, Trident Crossfire, and Trident X3/Crossfire Elevated Rim Acetabular Liners
• 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.

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.

Unitrax V40 Head, V40 Adapter Sleeve and C-Taper Adapter Sleeve
The HOWMEDICA OSTEONICS Unitrax Endoprosthesis, and the V40 Modular Adaptor sleeves are used as a hemiarthroplasty device for the following indications: femoral neck fractures, idiopathic avascular necrosis, and non-unions. The C-taper sleeves are intended for use as a Hemi-Hip Replacement with the following indications: femoral head/neck fractures or non-unions, aseptic necrosis of the femoral head/neck and osteo- and post traumatic arthritis. The patient's acetabular bone stock must be adequate to support articulation with the head of the endoprosthesis.

BIOLOX Delta Ceramic Heads (V40, C-Taper and Universal and C-Taper to Universal Taper Adapter Sleeve)
The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

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

Alumina C-Taper and V40 Ceramic Heads
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.
Additional indications for the Alumina C-Taper Ceramic Heads
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

Co Cr Femoral Heads (C-Taper and V40 Taper, LFIT and non-LFIT)
• 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.

Accolade C Femoral Stems, Accolade HFx Femoral Stems
Indications for use as a Total Hip Replacement 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.

Accolade TMZF and Accolade TMZF Plus Femoral Stems
The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a TMZF 5° 40’ trunnion.
Indications:
• Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.
• Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
• Revision procedures where other treatments or devices have failed.

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 Stryker Orthopaedics
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Date Prepared: October, 30, 2023

Proprietary Name: Stryker Orthopaedics Hip Systems 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

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR §888.3390

Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040

Bone fixation cerclage 21 CFR §888.3010

Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030

Product Codes:

LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer

LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous

JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented

LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented

KWL - prosthesis, hip, hemi-, femoral, metal

JDG - prosthesis, hip, femoral component, cemented, metal

KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented

MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish

MBL-prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous

HWC - screw, fixation, bone

JDQ - cerclage, fixation

HRS – plate, fixation bone

LRN – wire, surgical

LYT – fixation accessory

LZN - cement obturator

Legally Marketed Device to Which Substantial Equivalence is Claimed:

The primary predicate submission number is K153345, Stryker Orthopaedics Hip Systems Labeling Update.

Femoral Stem Components	
Exeter Femoral Stems (V40 taper)	K173499
SecurFit Max Femoral Stems	K153345
SecurFit Max Plus Femoral Stems	K153345
Accolade C Femoral Stems	K153345
Accolade TMZF Femoral Stems	K153345
Accolade TMZF Plus Femoral Stem	K153345
Accolade HFx Femoral Stem	K153345
Accolade II Femoral Stems	K153345
SecurFit Advanced Femoral Stems	K153345
Anato Femoral Stems	K153345
OmniFit HFx Femoral Stems	K153345
OmniFit EON Femoral Stems	K153345
Insignia Hip Stem	K220731
Restoration Modular Calcar Body	K212187
Restoration Modular Cone Body	K212187
Restoration Modular-Distal Bowed Stem-Plasma	K212187
Restoration Modular-Distal Stem-Conical	K212187
Restoration Modular-Distal Straight Stem-Plasma°	K212187
Restoration Modular 115mm Conical Distal Stem	K220731
Inserts/ Acetabular Liners	
ADM/MDM X3 Inserts (ETO), MDM X3 Insert	K182468
ADM/MDM X3 Inserts (GP)	K153345
MDM Acetabular Liners	K153345
Trident 0° Constrained Insert (multiple styles)	K153345
Trident 10° Constrained Insert	K153345

Trident Crossfire Inserts (multiple sizes)	K153345
Trident X3 Inserts (GP) multiple sizes	K153345
Trident X3 Acetabular Inserts (multiple styles)	K182468
Acetabular Shells, Augments, Dome Hole Plug	
Trident Hemispherical Shells (multiple configurations)	K153345
Tritanium Shells (multiple styles)	K153345
Restoration Anatomic Acetabular Shell	K210893
Trident Hemispherical Multi-Hole Shell	K153345
Tritanium Multi-Hole Shell	K153345
Trident HA PSL Solid Back Shell	K153345
Trident HA PSL Cluster Shell	K153345
Trident II Clusterhole HA Shell (multiple configurations)	K191358
Trident II Tritanium Shells (multiple styles)	K191358
Restoration Acetabular Augments	K153345
Acetabular Dome Hole Plug	K220376
Hex Dome Hole Plug	K191358
GAP II	K222632
Exeter X3 RimFit (GP) All Poly Cup	K213701
Exeter X3 RimFit (ETO) All Poly Cup	K213701
Femoral Heads and Adaptor Sleeves	
Biolox Delta Heads (Various sizes, styles)	K153345
Adapter Sleeves (Various Syles)	K153345
CoCR Heads (Various Styles/Sizes)	K153345
C-taper Alumina Ceramic Heads	K153345
V40 Orthinox Head	K173499
Unitrax V40 Head (38, 40-56, 58, 61) Unitrax V40 Adapter Sleeve Unitrax C-Taper Adapter Sleeve	K153345
UHR Bipolar	K222632
Acessory Devices, Screws	
Torx Screws	K153345
GAP Plate Screws	K153345

Osteolock Screws	K153345
UNIVERSAL CEMENT RESTRICTOR	K220838
6.5mm Low Profile Hex Screw	K191358
Artisan Bone Plug	K220838
Dall-Miles Trochanteric grip, cables, trochanteric grip plate, cable cleat (multiple configurations and styles)	K202016
Dall Miles Non-Beaded Cable	K202016
Dall-Miles Beaded Cable and Sleeve Set	K202016
Dall-Miles Non-Beaded Cable and Sleeve Set	K202016
Dall Miles Cable Sleeve sets (multiple styles/ configurations)	K202016
Dall-Miles Cable Set Cable Grip	K202016
Dall Miles Cable Sleeves	K202016
Exeter Centralizer	K191414
Exeter Intramedullary Plug	K191414
Universal Distal Cement Spacer	K153345

Device Description:

The devices covered by this submission are Stryker Total Hip components which include femoral stems, acetabular shells, liners, femoral heads, acetabular augments, acetabular bone screws, acetabular plugs, cables, trochanteric grips, cement restrictors, and distal femoral spacers. All devices are commercially available and have been cleared in prior 510(k) submissions.

All the subject devices have been cleared for MR conditional in previous 510(k)s. The purpose of this submission is to modify the MR conditional information in the instructions for use to update the parameters in which a patient who has the device can be safely scanned, per testing conducted accordance to updated FDA guidance. There have been no changes made to the devices requiring 510(k) clearance – only the MR conditional information in the instruction for use is being modified.

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

Indications:

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.

Universal Cement Restrictor, OmniFit Distal Cement Spacer

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.

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.

Trident® II Acetabular System (Trident II Cups (Clusterhole HA, PLS Clusterhold HA, Tritanium Clusterhole, Tritanium Multihole, Tritanium Solidback), 6.5mm Low Profile Hex Screw, Hex Dome Hole Plug

• 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 Liner:
• 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.

Restoration® Modular Hip System

The Restoration® Modular Hip System is indicated for use in:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis
- Correction of functional deformity;
- Revisions procedure 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

Additional indications specific to the Restoration Modular Hip System

The Restoration® Modular Hip System is intended to be used 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.

Accolade II Femoral Stems, Anato Femoral Stem, Secur-Fit Advanced

The indications for use for total hip arthroplasty with stems 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 fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Femoral Stem 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 intra-operative instability.

The Stems are intended for cementless use only and are intended for total and hemiarthroplasty.

TRIDENT AND TRITANIUM® ACETABULAR COMPONENTS

• 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.

The HOWMEDICA OSTEONICS TRIDENT and TRITANIUM Acetabular Shells are intended for cementless use only.

Dome hole plug is indicated for cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous

Acetabular Dome Hole Plug

The Dome Hole Plug is an optional device which is available to seal the Howmedica Osteonics Acetabular Shell components during cemented or cementless applications of the acetabular cup. The Howmedica Osteonics Done Hole Plug is threaded into the dome hole of the shell.

Indications

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

DALL-MILES® SYSTEMS

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.

Exeter® V40™ Hip System (includes Orthinox V40 Femoral heads)

The Exeter® V40™ Femoral Hip System is indicated for:

- 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® V40™ Femoral Stem Hip System is intended for use in total or hemi hip replacement. It is intended for cemented use only.

Exeter Centralizer, EXETER Intramedullary Plug

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

The Exeter 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. The Exeter Intramedullary Bone Plug 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.

Restoration GAP II Acetabular Shell

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

Segmental and/or cavitary acetabular defects which make it difficult to restore normal hip biomechanics or to reconstitute the normal structural continuity and integrity of the acetabulum, using standard total hip replacement acetabular components and procedures.

Gap Screws, Torx Screws, and Osteolock Bone Screws

HOWMEDICA OSTEONICS Torx Cancellous Bone Screws are intended for supplemental fixation of associated HOWMEDICA OSTEONICS cementless Acetabular Shells.

• HOWMEDICA OSTEONICS RESTORATION GAP Plate Screws are intended for fixation of the dome and iliac plates of the associated HOWMEDICA OSTEONICS RESTORATION GAP Acetabular Shell, TRIDENT TRITANIUM Hemispherical Multihole Acetabular Shells, restoration Acetabular Augments, and Restoration Anatomic shells.

Insignia Hip Stem

Hip Arthroplasty Indications:

- Painful, disabling joint disease of the hip resulting from: noninflammatory degenerative joint disease (including osteoarthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Revision of previous unsuccessful femoral head replacement, hip arthroplasty or other procedure.
- Correction of functional deformity
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of lnsignia Hip 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 intra-operative instability.

Additional indication specific to use of lnsignia Hip Stems with compatible ADM and MDM Acetabular Components:

- When the stem is to be used with compatible Howmedica Osteonics ADM and MDM Acetabular Components, the device is indicated for Dislocation risks

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

Omnifit HFX Femoral Stems

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.

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.
- Femoral neck fractures.

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 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.
- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

<u>Omnifit EON Cemented Femoral Stems</u>

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.

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.

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 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.

Indications for use as a Total Hip Replacement 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.

Restoration Anatomic Shell

• 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.

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 Liner:
• 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 Restoration® Anatomic Shell is indicated for cementless use only.

Trident Constrained Acetabular Insert/ Constrained Acetabular Insert

The Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Trident X3, Trident Crossfire, and Trident X3/Crossfire Elevated Rim Acetabular Liners

- 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.

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.

Unitrax V40 Head, V40 Adapter Sleeve and C-Taper Adapter Sleeve

The HOWMEDICA OSTEONICS Unitrax Endoprosthesis, and the V40 Modular Adaptor sleeves are used as a hemiarthroplasty device for the following indications: femoral neck fractures, idiopathic avascular necrosis, and non-unions. The C-taper sleeves are intended for use as a Hemi-Hip Replacement with the following indications: femoral head/neck fractures or non-unions, aseptic necrosis of the femoral head/neck and osteo- and post traumatic arthritis. The patient's acetabular bone stock must be adequate to support articulation with the head of the endoprosthesis.

BIOLOX Delta Ceramic Heads (V40, C-Taper and Universal and C-Taper to Universal Taper Adapter Sleeve)

The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

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

Alumina C-Taper and V40 Ceramic Heads

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.

Additional indications for the Alumina C-Taper Ceramic Heads

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

Co Cr Femoral Heads (C-Taper and V40 Taper, LFIT and non-LFIT)

- 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.

Accolade C Femoral Stems, Accolade HFx Femoral Stems

Indications for use as a Total Hip Replacement 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.

Accolade TMZF and Accolade TMZF Plus Femoral Stems

The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a TMZF 5° 40' trunnion.

Indications:

- Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.
- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Revision procedures where other treatments or devices have failed.

Summary of Technological Characteristics:

There have been no changes requiring 510(k) clearance to the technological characteristics of the Stryker Total Hip systems 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:

The Stryker Orthopedics Hip Systems have been previously evaluated and cleared for conditional use in a Magnetic Resonance Environment through non-clinical testing as outlined in Attachment CH3.08 - Performance Testing.

New testing has been performed to comprehensively assess the RF-related heating effects induced by the subject devices when implanted into bone, following the FDA guidance document, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," dated May 20, 2021.

The labeling of the Stryker Orthopedics Hip Systems has been modified to provide the parameters under which a patient who has the device can be safely scanned.

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

Conclusion: The Stryker Orthopaedics Hip System devices are substantially equivalent to the predicate device identified in this premarket notification.

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device.