July 25, 2025

Howmedica Osteonics Corp (dba Stryker Orthopaedics)
Gregg Ritter
Senior Principle Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K250989
Trade/Device Name: Stryker and Serf hip devices
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, MAY, MBL, HWC
Dated: March 31, 2025
Received: June 27, 2025

Dear Gregg Ritter:

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,

RYAN TROMBETTA -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

Indications for Use

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

510(k) Number *(if known)*
K250989

Device Name
Stryker and Serf hip devices

Indications for Use *(Describe)*
Restoration ADM and MDM Systems (ADM/MDM X3 Inserts, MDM Acetabular Inserts, MDM Acetabular Liners)
Indications for Use:
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.
…
Trident II Acetabular System (Trident II Cups (Clusterhole HA, PLS Clusterhold HA, Tritanium Clusterhole, Tritanium Multihole, Tritanium Solidback)
Indications for Use:
• 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;
• 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 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.
…
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 procedures.
...
Accolade II Femoral 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 the 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 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
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...
V40 COBALT-CHROME (COCR) FEMORAL HEADS (LFIT V40™ Femoral Heads)
• 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.
…
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.
…
Restoration Anatomic Shells
Indications for Use
• 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 X3, Trident X3 Elevated Rim, Trident X3 Eccentric Inserts)
Indications for Use:
• 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.

…
BIOLOX Delta Ceramic V40 Femoral Heads (V40)

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

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...
“D” femoral heads
• The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:
- osteoarthritis,
- femoral neck fracture,
- dislocation risk,
- osteonecrosis of the femoral head,
- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.
• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.
• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.
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“C” femoral heads
The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:
- osteoarthritis,
- femoral neck fracture,
- dislocation risk,
- osteonecrosis of the femoral head,
- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.
• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.
• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.
...
Hype® SC cementless hip stems
The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:
- osteoarthritis,
- femoral neck fracture,
- dislocation risk,
- osteonecrosis of the femoral head,
- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.
• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular

cup is indicated for cemented use.
• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.
...
Novae® dual mobility acetabular cup range including Novae® cementless or cemented metal-backs, CI E and XPEO-E liners, pegs and VCI screws
• Novae® dual mobility acetabular cups are indicated for total hip replacement, which includes:
- osteoarthritis,
- femoral neck fracture,
- dislocation risk,
- osteonecrosis of the femoral head,
- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.
• "Sunfit TH", "Novae E TH" and "Coptos TH" acetabular cups are intended for press-fit use.
• Novae® Stick acetabular cup is intended for cemented use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor Howmedica Osteonics Corp (dba Stryker Orthopaedics)
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Mahwah, NJ 07430

Contact Person Gregg Ritter
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gregg.ritter@stryker.com

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Mahwah, NJ 07430
(201) 831-5559

Date Prepared: July 25, 2025

Proprietary Name: Stryker and Serf hip devices

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/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353
Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR §888.3310
Screw/Fixation/Bone 21 CFR §888.3040

Product Codes:
LPH, KWZ, LZO, MEH, MAY, MBL, HWC

Legally Marketed Primary Predicate Device to Which Substantial Equivalence is Claimed:
Submission Number: K243784
Device Name: Stryker Orthopaedics Hip Systems Labeling Update

Legally Marketed Additional Predicate Device Used to Support Substantial Equivalence:

Submission Number: K233498
Device Name: Stryker Orthopaedics Hip Systems Labeling Update

Submission Number: K223745
Device Name: Novae® Dual Mobility System, Hype® Hip System

Submission Number: K111572
Device Name: NOVAE SUNFIT TH DUAL MOBILITY ACETABULAR CUP MODEL SUNFIT TH (METAL-BACK), NOVAE E TH DUAL MOBILITY ACETABULAR CUP MODEL

Reason for 510(k) Submission:
The purpose of this submission is to provide updated labeling for the Stryker and Serf hip system devices to inform users of compatibility between components from each manufacturer. Verification analyses to substantiate the compatibilities are also included. Lastly, the Serf labeling is being updated to include magnetic resonance safety information for the products that did not previously include it and for the combination with Stryker devices. There are no changes to the design, materials, sterilization, or packaging of the subject devices as compared to the previously cleared versions.

Device Description:
The devices covered by this submission are Stryker and Serf femoral stems, femoral heads, acetabular shells and liner, and Serf acetabular bone screw, to form traditional hip or dual mobility (DM) hip systems. 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:
Restoration ADM and MDM Systems (ADM/MDM X3 Inserts, MDM Acetabular Inserts, MDM Acetabular Liners)

Indications for Use:

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.

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Trident II Acetabular System (Trident II Cups (Clusterhole HA, PLS Clusterhold HA, Tritanium Clusterhole, Tritanium Multihole, Tritanium Solidback)

Indications for Use:

- 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.

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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;
- 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 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.

…

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 procedures.

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Accolade II Femoral 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 the 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 intra- operative instability.

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

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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

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V40 COBALT-CHROME (COCR) FEMORAL HEADS (LFIT V40™ Femoral Heads)

- 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.

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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.

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Restoration Anatomic Shells

Indications for Use

- 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.

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Trident X3, Trident X3 Elevated Rim, Trident X3 Eccentric Inserts)

Indications for Use:

- 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.

…

BIOLOX Delta Ceramic V40 Femoral Heads (V40)

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

...

“D” femoral heads

The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:

- osteoarthritis,

- femoral neck fracture,

- dislocation risk,

- osteonecrosis of the femoral head,

- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.

• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.

• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.

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“C” femoral heads

The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:

- osteoarthritis,

- femoral neck fracture,

- dislocation risk,

- osteonecrosis of the femoral head,

- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.

• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.

• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.

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Hype® SC cementless hip stems

The Novae® Dual Mobility and Hype® hip Systems are indicated for total hip replacement, which includes:

- osteoarthritis,

- femoral neck fracture,

- dislocation risk,

- osteonecrosis of the femoral head,

- revision procedures where other treatments or devices have failed and if bone reconstruction so permits.

• Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.

• Hype® SCS, SCC, SCL, SCV, SCC Mini, and SCLA Mini hip stems are intended for press-fit use.

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Novae® dual mobility acetabular cup range including Novae® cementless or cemented metal-backs, CI E and XPEO-E liners, pegs and VCI screws

- Novae® dual mobility acetabular cups are indicated for total hip replacement, which includes:
  - osteoarthritis,
  - femoral neck fracture,
  - dislocation risk,
  - osteonecrosis of the femoral head,
  - revision procedures where other treatments or devices have failed and if bone reconstruction so permits.
- "Sunfit TH", "Novae E TH" and "Coptos TH" acetabular cups are intended for press-fit use.
- Novae® Stick acetabular cup is intended for cemented use.

Summary of Technological Characteristics:
There have been no changes requiring 510(k) clearance to the technological characteristics of the subject devices as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:
Performance of the subject combinations of Stryker and Serf hip devices were evaluated in a series of engineering analyses. These included wear and articular surface tolerances, impingement, range of motion, femoral head disassembly, and MR safety (including heating, displacement, induced torque, and image artifact).

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, material, sterilization method, technical and performance characteristics, and operational principles, the Stryker and Serf subject hip devices, when used in the proposed compatible combinations with each other, are substantially equivalent to the predicate devices identified in this premarket notification.