July 10, 2026

Howmedica Osteonics Corp., DBA Stryker Orthopaedics
Elizabeth Jodon
Principal Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K261624
Trade/Device Name: Omnifit® 20 Series I Insert; Omnifit® Crossfire® 10 Series II Insert; Constrained Acetabular Insert; Trident® Crossfire® 0 Polyethylene Insert; Trident ® Crossfire ® 10 Polyethylene Insert; System 12 Crossfire® 10 Insert; Trident® 0 Constrained Acetabular Insert; Trident® Constrained Acetabular Liner; Trident® All Poly Constrained Acetabular Insert; Crossfire® Eccentric Insert 10; Artisan® Bone Plug; UHR® Universal Head Bipolar Component
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, KWL, LWJ, LZO, MEH, KWZ, JDI, LZN
Dated: May 15, 2026
Received: May 15, 2026

Dear Elizabeth Jodon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-

devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LIMIN SUN -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261624

Please provide the device trade name(s).

Omnifit® 20° Series I Insert;
Omnifit® Crossfire® 10° Series II Insert;
Constrained Acetabular Insert;
Trident® Crossfire® 0° Polyethylene Insert;
Trident ® Crossfire ® 10° Polyethylene Insert;
System 12 Crossfire ® 10° Insert;
Trident ® 0° Constrained Acetabular Insert;
Trident® Constrained Acetabular Liner;
Trident® All Poly Constrained Acetabular Insert;
Crossfire® Eccentric Insert 10°;
Artisan® Bone Plug;
UHR® Universal Head Bipolar Component

Please provide your Indications for Use below.

Omnifit® 20° Series I Insert, Omnifit® Crossfire® 10° Series II Insert, Omnifit® Crossfire® 10° Eccentric Insert, Trident® Crossfire 0° and 10° Polyethylene Insert
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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Constrained Acetabular Insert, Trident® 0° Constrained Acetabular Insert, Trident® Constrained Acet. Liner, Trident® All Poly Constrained Acetabular Insert
Indications for Use:

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

System 12 Crossfire® 10° Insert
Indications for Use:

- 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

Artisan® Bone Plug
Indications for Use:

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.

UHR® Universal Head Bipolar Component
Indications for Use:

- 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Sponsor Stryker Orthopaedics
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Date Prepared: 09-July-2026

Proprietary Name:
Omnifit® 20° Series I Insert
Omnifit® Crossfire® 10° Series II Insert
Constrained Acetabular Insert
Trident® Crossfire® 0° Polyethylene Insert
Trident® Crossfire® 10° Polyethylene Insert
System 12 Crossfire® 10° Insert
Trident® 0° Constrained Acetabular Insert
Trident® Constrained Acetabular Liner
Trident® All Poly Constrained Acetabular Insert
Crossfire® Eccentric Insert 10°
Artisan® Bone Plug
UHR® Universal Head Bipolar Component

Common Name: Artificial Hip Replacement Components – Acetabular and Femoral

Classification Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis (21CFR § 888.3358)

Hip Joint Femoral (hemi-hip) Metallic Cemented or Uncemented Prosthesis. (21 CFR § 888.3360)

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)

Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis (21 CFR §888.3350)

Surgical Mesh (21 CFR §878.3300)

Product Codes: LPH, KWL, LWJ, LZO, MEH, KWZ, JDI, LZN

Legally Marketed Primary Predicate Device to Which Substantial Equivalence is Claimed:

The primary predicate for this submission is K243784

Legally Marketed Additional Predicate Device Used to Support Substantial Equivalence:

Device	Previous Premarket Notifications
Omnifit® 20° Series I Insert	K900438 K243784
Omnifit® Crossfire® 10° Series II Insert	K974685 K243784 K890197
Constrained Acetabular Insert	K890197
Trident® Crossfire® 0° Polyethylene Insert	K983382 K983502 K991952 K021911 K233498 K243784
Trident® Crossfire® 10° Polyethylene Insert	K983382 K983502 K991952 K021911 K233498 K243784

Device	Previous Premarket Notifications
System 12 Crossfire® 10° Insert	K993352 K121308 K243784
Trident® 0° Constrained Acetabular Insert Trident® Constrained Acetabular Liner Trident® All Poly Constrained Acetabular Insert	K061654 K233498 K243784
Omnifit® Crossfire® 10° Eccentric Insert	K974685 K243784
Artisan® Bone Plug	K951860 K220838 K233498 K243784
UHR® Universal Head Bipolar Component	K800207 K910988 K993601 K173499 K222632 K233498 K243784

Rationale for Bundling:

The change proposed is related to updating the packaging configuration of the Ultra High Molecular Weight Polyethylene (UHMWPE) hip devices that are packaged in a Nitrogen Vacuum (N_2Vac) environment. The same proposed packaging configurations may be used among multiple generic product types, and the same supporting data can be used across all product types. In all testing performed to support the proposed packaging change, worst-case devices, representative of all products, were used. Therefore, the testing data represent all products currently bundled in the subject 510(k) submission.

Device Description:

The devices covered by this Traditional 510(k) Premarket Notification are Stryker Ultra High Molecular Weight Polyethylene (UHMWPE) hip devices (including femoral heads, bone plugs, acetabular inserts and liners) that are packaged in a Nitrogen Vacuum (N_2Vac) environment. The packaging for these devices consists of an impermeable foil pouch in a Polyethylene Terephthalate Glycol (PETG) blister sealed with a Tyvek lid. All subject devices are commercially available and have been found to be substantially equivalent in previous 510(k)s.

Intended Use:

The subject devices have the same intended use as those specified in the 510(k) submissions for the predicate devices listed. In general, these devices are intended for use in primary or revision hip arthroplasty.

Indications for Use:

Omnifit® 20° Series I Insert, Omnifit® Crossfire®10° Series II Insert, Omnifit® Crossfire® 10° Eccentric Insert, Trident® Crossfire 0° and 10° Polyethylene Insert
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.
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Indications for Use:

- 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

Summary of Technological Characteristics:

The subject devices are equivalent in intended use, indications for use, product design, product materials, and operational principles to their corresponding predicates. The only difference between the subject devices and corresponding predicate devices is their packaging configurations. The packaging components of the predicate devices contain an inner and outer blister of Barex® Modified Acrylonitrile copolymer sealed with inner and outer foil lids purged with alternating vacuum and nitrogen (N_2Vac). The packaging of the subject devices consist of an impermeable foil pouch in a Polyethylene Terephthalate Glycol (PETG) blister sealed with a Tyvek lid followed by vacuum and nitrogen (N_2Vac) purging. The labeling updates in this submission have no impact on the technological characteristics of the subject and predicate devices.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial equivalence:

Studies were performed on the subject UHMWPE hip devices to evaluate the effect of the proposed packaging modifications. The studies compared the following material properties of the subject UHMWPE devices for the proposed and current packaging configurations:

- Small Punch per ASTM F2977
- Oxygen Content
- Oxidation Index per ASTM F2102

Design Verification Distribution (ship) and Packaging Performance testing were completed on the subject devices to qualify the proposed packaging configurations. Testing was completed per ISO 11607-1, ASTM F88 / F88M, and ASTM F2096.

Accelerated Aging studies were completed to validate a shelf-life of five (5) years (inclusive of final month) for the subject devices marketed as STERILE per ISO 11607-1, ISO 11607-2, and ASTM F1980.

Product endotoxin and cytotoxicity testing were executed as the proposed packaging configuration constitutes a change in packaging materials that contact the product after final cleaning. Endotoxin testing was completed per AAMI ST72, and cytotoxicity testing was completed per ISO 10993-5.

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 subject devices are substantially equivalent to the predicate devices identified in this Premarket Notification.