February 6, 2025

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Tara Rudrapatna
Regulatory Affairs Staff Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K243817
Trade/Device Name: Scorpio Universal Dome Patella; Scorpio Total Stabilizer Insert; Scorpio-Flex Posterior Stabilized Tibial Insert; Scorpio-Flex Cruciate Retaining Tibial Insert; Scorpio NRG Tibial Bearing Insert - Cruciate Retaining Insert; Scorpio NRG Tibial Bearing Insert - Posteriorly Stabilized Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 9, 2024
Received: December 12, 2024

Dear Tara Rudrapatna:

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,

Lixin Liu -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K243817

Device Name
Scorpio-Flex Cruciate Retaining Tibial Insert; Scorpio NRG Tibial Bearing Insert – Posteriorly Stabilized Insert; Scorpio-Flex Posterior Stabilized Tibial Insert; Scorpio NRG Tibial Bearing Insert – Cruciate Retaining Insert; Scorpio Universal Dome Patella; Scorpio Total Stabilizer Insert

Indications for Use *(Describe)*
Indications for the Scorpio-Flex Cruciate Retaining Tibial Insert:
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure

Indications for the Scorpio NRG Tibial Bearing Insert – Posteriorly Stabilized Insert:
The Scorpio NRG Knee system components are for use in total knee arthroplasty as a result of:
• Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure
Additional indications for the Posterior stabilized components include:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament.

Indications for the Scorpio-Flex Posterior Stabilized Tibial Insert:
• Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function; moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament.

Indications for the Scorpio NRG Tibial Bearing Insert – Cruciate Retaining Insert:
The Scorpio NRG Knee system components are for use in total knee arthroplasty as a result of
• Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure
Additional Indications for Posterior Stabilized Devices:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament.

Indications for the Osteonics Scorpio Universal Dome Patella:
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic

arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure

Indications for the Scorpio Total Stabilizer Insert:
General TKR Indications
• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
• Revision of previous unsuccessful knee replacement or other procedure
Additional Indications for Posterior Stabilized (PS) or Total Stabilized (TS) Components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament
• Severe anteroposterior instability of the knee joint
• For Total Stabilizer (TS) Components Only: Severe instability of the knee secondary to compromised collateral ligament integrity or function
Indications for Bone Augmentation Wedges:
• Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss
• Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss

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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K243817

510(k) Summary

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Date Prepared: 5-Feb-2025

Proprietary Name:

Scorpio Universal Dome Patella
Scorpio Total Stabilizer Insert
Scorpio-Flex Posterior Stabilized Tibial Insert
Scorpio-Flex Cruciate Retaining Tibial Insert
Scorpio NRG Tibial Bearing Insert – Cruciate Retaining Insert
Scorpio NRG Tibial Bearing Insert – Posteriorly Stabilized Insert

Common Name: Total Knee Replacement System, Tibial Inserts, Patellar components

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. (21 CFR § 888.3560)

Product Codes: JWH

Primary Predicate Device to Which Substantial Equivalence is Claimed:
Submission Number: K994128
Device Name: Scorpio Total Stabilizer (TS) Total Knee System
Product Codes: JWH

Additional Predicate Devices Used to Support Substantial Equivalence:

Submission Number	Device Name	Product Codes
K041591	Scorpio-flex Posterior Stabilized Tibial Insert Components	JWH
K011643	Scorpio Cr Superflex Tibial Insert	JWH
K030978	Scorpio NRG Knee System	JWH
K042343	Scorpio NRG Knee System	JWH
K972967	Osteonics Scorpio Total Knee Universal Dome Patellar Component; Osteonics Scorpio Total Knee Recessed Patellar Component	JWH

Reason for 510(k) Submission:

The purpose of this "Change Being Effected" bundled submission is to add a contraindication to the labeling of the subject Scorpio Total Knee System.

Device Description:

The devices included in this submission are tibial inserts, and all-polyethylene patellar components used in total knee arthroplasty procedures. All devices have been previously deemed substantially equivalent in prior premarket submissions and are commercially available.

Intended Use:

The Stryker Scorpio Total Knee system components are intended for the replacement of the bearing and/or articulating surfaces of the distal femur and proximal tibia to remove pain, instability, and restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma. The devices are intended for single-use only, and are intended for cemented fixation in patients indicated for total knee arthroplasty.

Indications:

Indications for the Scorpio-Flex Cruciate Retaining Tibial Insert:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

Indications for the Scorpio NRG Tibial Bearing Insert – Posteriorly Stabilized Insert:
The Scorpio NRG Knee system components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Additional indications for the Posterior stabilized components include:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament.

Indications for the Scorpio-Flex Posterior Stabilized Tibial Insert:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function; moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament.

Indications for the Scorpio NRG Tibial Bearing Insert – Cruciate Retaining Insert:
The Scorpio NRG Knee system components are for use in total knee arthroplasty as a result of

- Painful, disabling joint disease of the knee resulting from degenerative arthritis; rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Additional Indications for Posterior Stabilized Devices:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament.

Indications for the Osteonics Scorpio Universal Dome Patella:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

Indications for the Scorpio Total Stabilizer Insert:

General TKR Indications

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

Additional Indications for Posterior Stabilized (PS) or Total Stabilized (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint
- For Total Stabilizer (TS) Components Only: Severe instability of the knee secondary to compromised collateral ligament integrity or function

Indications for Bone Augmentation Wedges:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

Indications for the Scorpio Total Stabilizer Insert:

General TKR Indications

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligaments structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Additional Indications for Posterior Stabilized (PS) or Total Stabilized (TS) Components:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint

- For Total Stabilizer (TS) Components Only: Severe instability of the knee secondary to compromised collateral ligament integrity or function

Indications for Bone Augmentation Wedges:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss

Summary of Technological Characteristics:

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

Non-Clinical Testing:

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

Clinical Testing:

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

Conclusion:

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