August 6, 2026

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

Re: K261898
Trade/Device Name: Triathlon® Knee System; Triathlon® Hinge Knee System; Scorpio® Total Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JWH, MBH
Dated: June 2, 2026
Received: June 5, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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

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)*
K261898

Device Name
Triathlon® Knee System; Triathlon® Hinge Knee System; Scorpio® Total Knee System

Indications for Use *(Describe)*

Triathlon® Knee System

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use. The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (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.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- 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.

Additional Indications for Cone Augments:

- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

Triathlon® Hinge Knee System

Triathlon® Hinge Knee System is intended to be implanted with bone cement for the following condition(s):

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak. And/or
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with MRH femur and/or MRH tibial baseplate replacement indicated in revision of an existing prosthesis:

- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with compatible GMRS components:

- Where segmental resection and/or replacement of femur and/or proximal tibia is required

Scorpio® Total Knee System

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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510(k) Summary

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Date Prepared: 04-August-2026

Proprietary Name: Triathlon® Knee System;
Triathlon® Hinge Knee System;
Scorpio® Total Knee System

Common Name: Artificial Knee Replacement Components – Tibial Inserts and All Poly Tibial Components

Classification Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR §888.3510)

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

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR §888.3565)

Primary Product Code: KRO

Subsequent Product Codes: JWH, MBH

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

Primary predicate: K242831

Device Name: Triathlon Knee System

Product Code: JWH

Legally Marketed Additional Predicate Device Used to Support Substantial Equivalence:

Device	Previous Premarket Notifications
Triathlon® Knee System	
Tibial Inserts	
Triathlon® Tibial Bearing Insert - CR (Cruciate Retaining Insert)	K040267 K042883 K141056 K172326 K173849 K201343 K242831
Triathlon® Tibial Bearing Insert - CS (Condylar Stabilizing Insert)	K063423 K141056 K172326 K173849 K201343 K242831
Triathlon® Tibial Bearing Insert - PS (Posterior Stabilized Insert)	K031729 K050539 K141056 K173849 K172326 K201343 K242831
Triathlon® All Poly Tibial Component - CS (Condylar Stabilizing Insert)	K123166 K141056 K172326 K201343 K242831
Triathlon® All Poly Tibial Component - PS (Posterior Stabilized Insert)	K123166 K141056 K172326 K201343 K242831
Triathlon® Hinge Knee System	
Hinge Knee Tibial Components	
Triathlon® Bushing and Axle STD	K230416 K251665
Triathlon® Hinge Insert with Sleeve	K223528 K230416 K251665
Scorpio® Total Knee System	
Tibial Inserts	
Scorpio-Flex™ Posterior Stabilized Tibial Insert	K041591 K243817
Scorpio-Flex™ Cruciate Retaining Tibial Insert	K011643 K243817
Scorpio® NRG® Tibial Bearing Insert – Cruciate Retaining Insert	K042343 K243817
Scorpio® NRG® Tibial Bearing Insert – Posterior Stabilized Insert	K030978 K243817

Legally Marketed Reference Devices Used to Support scientific methodology or standard reference values in terms of testing and labeling in the Magnetic Resonance (MR) Environment:

K242831 – Triathlon® Knee System and K230416 – Triathlon® Hinge Knee System.

The Scorpio Total Knee System has not been evaluated for safety and compatibility in the MR environment."

Legally Marketed Reference Devices Used to Support scientific methodology or standard reference values in terms of Packaging Configuration Update: K252898 - Triathlon® Tritanium® Asymmetric Patella; Triathlon® Tritanium® Symmetric Patella; Triathlon® Symmetric Patella; Triathlon® Asymmetric Patella; Scorpio® Universal Dome Patella; Triathlon® Hinge Bumper.

Rationale for Bundling:

The change proposed is related to updating the packaging configuration of the Ultra High Molecular Weight Polyethylene (UHMWPE) knee 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 represents 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) knee devices (Tibial Inserts and All-Poly Tibial Components) 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 knee arthroplasty.

Indications:

Triathlon® Knee System

General Total Knee Arthroplasty (TKR) Indications:

• Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.

• Post-traumatic loss of knee joint configuration and function.

• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Revision of previous unsuccessful knee replacement or other procedure.
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture - management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.
The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.
The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (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.

Additional Indications for Total Stabilizer (TS) Components:
• Severe instability of the knee secondary to compromised collateral ligament integrity or function.
Indications for Bone Augments:
• 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.

Additional Indications for Cone Augments:
• Severe degeneration or trauma requiring extensive resection and replacement
• Femoral and Tibial bone voids
• Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

<u>Triathlon® Hinge Knee System</u>
Triathlon® Hinge Knee System is intended to be implanted with bone cement for the following condition(s):

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak. And/or
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with MRH femur and/or MRH tibial baseplate replacement indicated in revision of an existing prosthesis:

- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with compatible GMRS components:

- Where segmental resection and/or replacement of femur and/or proximal tibia is required.

Scorpio® Total Knee System

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

Summary of Technological Characteristics:

The subject devices are substantially 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[â] 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.

Non-Clinical Testing:

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

Studies were performed on the subject UHMWPE knee 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.