



June 28, 2024

MicroPort Orthopedics Inc.  
Ryan Ross  
Sr. Regulatory Manager  
5677 Airline Road  
Arlington, Tennessee 38002

Re: K240043

Trade/Device Name: EVOLUTION® Hinge Knee System; GUARDIAN™ limb Salvage System; DCW Modular Distal Femoral System; REPIPHYSIS™ Limb Salvage System; EVOLUTION® MP Total Knee System; EVOLUTION® MP Total Knee System; EVOLUTION® MP Adaptive CS Insert; EVOLUTION® MP Adaptive PS Tibial Insert; EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts; EVOLUTION® Revision CCK System; ADVANCE® Double High Insert; ADVANCE® A-CLASS® Tibial Insert; ADVANCE® Knee System; ADVANCE® Ultra-Congruent Tibial Insert; ADVANCED® Revision Product Line Extension; ADVANCE® Total Knee System-Patella; ADVANCE® Tibial Component; Whiteside Condylar II Total Knee Prosthesis; Whiteside ORTHOLOC™; Whiteside ORTHOLOC® M.A. Total Knee System; AXIOM® Total Knee Syst/ACL Retain Tibial Tray/Insert; AXIOM® Total Knee System, A/P Curved Tibial Insert; Second GENERATION KNEE SYSTEM; Whiteside ORTHOLOC® Modular Post. Stab. Knee System; AXIOM® Total Knee System; Thick Tibial Insert; Insall-Burstein II; ORTHOLOC® ADVANTIM® PS LSI Tibial Insert; ULTRACK 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, MBH, JWH, HRY, HSX

Dear Ryan Ross:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on April 1, 2024. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lixin Liu, OHT6: Office of Orthopedic Devices, 301-796-3480, [Lixin.Liu@fda.hhs.gov](mailto:Lixin.Liu@fda.hhs.gov).

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



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Regulation Number: 21 CFR 888.3510

Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis

Regulatory Class: Class II

Product Code: KRO, MBH, JWH, HRY, HSX

Dated: January 5, 2024

Received: January 5, 2024

Dear Ryan Ross:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on April 1, 2024.

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the

provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

[devices/device-advice-comprehensive-regulatory-assistance](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Lixin Liu -S**

Lixin Liu, PhD

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

510(k) Number (if known)

K240043

Device Name

EVOLUTION® Hinge Knee System

Indications for Use (Describe)

The EVOLUTION® Hinge Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- 1) Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) Inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) Correction of functional deformity;
- 4) Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Hinge Knee System implants are for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

GUARDIAN™ Limb Salvage System

Indications for Use (Describe)

GUARDIAN™ Limb Salvage Hip Components:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

- 1) patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
- 2) surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications.
- 3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

The GUARDIAN™ Limb Salvage Knee Components:

Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal tibia is required with the following conditions:

- 1) patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
- 2) surgical intervention for severe trauma, revision knee arthroplasties, and/or Oncology indications.
- 3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

DCW MODULAR DISTAL FEMORAL SYSTEM

Indications for Use (Describe)

The DCW Modular Distal Femoral System is primarily indicated for procedures in which a variable resection length prosthesis is necessary to accommodate the condition of the femur, e.g. bone loss/removal in disease-related knee arthroplasty or a distally fractured femur. It is also indicated for revision of a previous total knee replacement where the femoral prosthesis has loosened, broken, or requires surgical removal for another medical reason. These indications are intended to provide relief of pain and restoration of knee function in skeletally mature patients.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
REPIPHYSIS™ Limb Salvage System

### Indications for Use (Describe)

Limb salvage surgery is indicated for cemented procedures where radical resection and replacement of the distal femur and/or proximal tibia is required with the following conditions:

1. patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2. surgical intervention for severe trauma, revision knee arthroplasties, and/or oncology indications.
3. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

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)

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## Indications for Use

510(k) Number (if known)  
K240043

### Device Name

EVOLUTION® MP Total Knee System, EVOLUTION® MP Adaptive CS Insert, EVOLUTION® MP Adaptive PS Tibial Insert, EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts, EVOLUTION® Revision CCK System

### Indications for Use (Describe)

The EVOLUTION® MP Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. inflammatory degenerative joint disease including rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Total Knee System nonporous components are for cemented use only.

The EVOLUTION® Total Knee System porous components are for use without bone cement.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

### Device Name

ADVANCE® Double High Insert, ADVANCE® A-CLASS Tibial Insert, ADVANCE® Knee System, ADVANCE® Ultra-Congruent Tibial Insert, ADVANCED® Revision Product Line Extension, ADVANCE® Total Knee System-Patella, ADVANCE® Tibial Component

### Indications for Use (Describe)

The ADVANCE® Total Knee System components are indicated for use in total knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 5) treatment of fractures that are unmanageable using other techniques.

The ADVANCE® Total Knee System is for single use. The Advance Total Knee System porous components are for use without bone cement. The Advance Total Knee System non-porous components are for use with bone cement.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
Whiteside Condylar II Total Knee Prosthesis

### Indications for Use (Describe)

The Whiteside Condylar II™ Total Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis or inflammatory arthritis or traumatic arthritis, with or without moderate valgus, varus, or flexion deformities. The prosthesis is also indicated for revision of a failed prosthesis where the posterior cruciate and collateral ligaments are intact. The device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
Whiteside ORTHOLOC

### Indications for Use (Describe)

The Whiteside ORTHOLOC™ Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities, where posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. The prosthesis is also indicated for revision of a failed prosthesis where the cruciate ligaments are absent but the collateral ligaments are intact. The device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
Whiteside ORTHOLOC M.A. Total Knee System

### Indications for Use (Describe)

The Whiteside ORTHOLOC® M.A. Total Knee System is indicated for use in conjunction with the metal tibial base of the Whiteside ORTHOLOC® II Total Knee System for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental or tricompartmental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the posterior cruciate and collateral ligaments are intact. The prosthesis is also indicated for revision of a failed prosthesis where the posterior cruciate and collateral ligaments are intact. The device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
AXIOM Total Knee Syst/ACL Retain Tibial Tray/Insert

### Indications for Use (Describe)

The AXIOM ACL Retaining Tibial Tray and Tibial Insert are used in total knee arthroplasty for replacement of the tibial plateau of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. AXIOM ACL Retaining Tibial Tray and Tibial Insert are for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

AXIOM Total Knee System, A/P Curved Tibial Insert

Indications for Use (Describe)

The A/P Curved Tibial Insert is used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. The A/P Curved Tibial Insert is intended for cemented application only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
Second Generation Knee System

### Indications for Use (Describe)

The Second Generation Knee System is used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. The Second Generation Knee System is intended for cemented application only.

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

Whiteside ORTHOLOC Modular Post. Stab. Knee System

Indications for Use (Describe)

The Whiteside ORTHOLOC® Modular Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities, where the posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. This prosthesis is also indicated for revision of a failed prosthesis, where the cruciate ligaments are absent. This device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
AXIOM Total Knee System

### Indications for Use (Describe)

The Modular Femoral Component and Constrained Tibial insert are used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. Additional indications specific to the Modular Femoral Component and Constrained Tibial Insert include use in patients with anterior/posterior, varus/valgus, and rotational joint instability resulting from inadequate or absent cruciate and collateral ligaments, or who's knee can not be stabilized by usual soft tissue management. This device is intended for single use in a cemented application only.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
Thick Tibial Insert

### Indications for Use (Describe)

The ORTHOLOC® Tibial Plastic Insert, as part the ORTHOLOC® Total Knee System, is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the posterior cruciate and collateral ligaments are intact. The system is also indicated for revision of failed prosthesis where the posterior cruciate and collateral ligaments are intact. This device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

Insall-Burstein II

Indications for Use (Describe)

Total knee arthroplasty has been proved effective in reducing or relieving pain and in restoring functional knee motion. Such surgical procedures have been used in the management of: painful disabling bicompartamental joint disease secondary to osteoarthritis, rheumatoid, or traumatic arthritis; posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus or flexion deformities. The device may also be indicated in the salvage of previously failed surgical attempts. This device is intended for cemented use only.

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)

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## Indications for Use

510(k) Number (if known)

K240043

Device Name

ORTHOLOC ADVANTIM PS LSI Tibial Insert

Indications for Use (Describe)

The ORTHOLOC® ADVANTIM™ Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental or tricompartmental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. This prosthesis is also indicated for revision of a failed prosthesis, where the cruciate ligaments are absent.

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)

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## Indications for Use

510(k) Number (if known)  
K240043

Device Name  
ULTRACK Total Knee System

### Indications for Use (Describe)

The ULTRACK™ Total Knee System is intended for bicompartamental or tricompartmental replacement of the knee joint for reduction of pain or increased function for the following conditions:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) Inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) Correction of functional deformity;
- 4) Revision procedures where other treatments or devices have failed; and
- 5) Treatment of fractures that are unmanageable using other techniques.

This device is intended for cemented use only.

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)

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## 510(k) Summary of Safety and Effectiveness

**Submitted by:** MicroPort Orthopedics Inc.  
5677 Airline Rd, Arlington TN, 38002  
USA  
Phone: 866-872-0211  
Fax: 855-446-2247

**Date:** March 29, 2024

**Contact Person:** Ryan Ross, Sr. Manager, Regulatory Affairs

**Proprietary Name:** EVOLUTION® Hinge Knee System  
GUARDIAN™ Limb Salvage System  
DCW Modular Distal Femoral System  
REPIPHYSIS™ Limb Salvage System

**Common Name:** Hinge Knee System  
Limb Salvage System

**Classification Name and Reference:** 21 CFR 888.3510 – Knee joint femorotibial metal/polymer constrained cemented prosthesis  
Class II

**Primary Product Code and Panel Code:** Orthopedics/87/ KRO

**Primary Predicate Device:** EVOLUTION® Hinge Knee System (K230563)

**Additional Predicates:** GUARDIAN™ Limb Salvage System (K013035)  
DCW Modular Distal Femoral System (K910596)  
REPIPHYSIS™ Limb Salvage System (K021489)

**DEVICE INFORMATION**

The purpose of this bundled submission is to notify of a change in ethylene oxide (EO) sterilization supplier taking place, affecting all MicroPort Orthopedics UHMWPE and combination metal/UHMWPE knee system implants. The subject devices consist of multiple devices across multiple systems. The subject devices are identical to the predicate devices in all aspects, and the only change is to the sterilization supplier and sterilization parameters. The subject devices included in this Traditional 510(k) Premarket Notification have been bundled in accordance with “*Bundling Multiple Devices or Multiple Indications in a Single Submission; Guidance for Industry and Food and Drug Administration Staff*” issued on June 22, 2007. Per assessment of the guidance document, MicroPort Orthopedics Inc. has determined the devices bundled in this submission are appropriate as the supporting data are similar, one review division/group is involved, and the devices or indications for use are similar. All subject devices included in this submission are similar devices that undergo the same sterilization process, are affected by the same supplier and parameter changes, and the change is supported by similar validations and assessments.

**A. Intended Use/Indications for Use Statement**

**Device Name:** EVOLUTION® Hinge Knee System

**Indications:**

The EVOLUTION® Hinge Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- 1) Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) Inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) Correction of functional deformity;
- 4) Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Hinge Knee System implants are for cemented use only.

**Device Name:** GUARDIAN™ Limb Salvage System

**Indications:**

GUARDIAN™ Limb Salvage Hip Components:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

- 1) patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
- 2) surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications.
- 3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

The GUARDIAN™ Limb Salvage Knee Components:

Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal tibia is required with the following conditions:

- 1) patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
- 2) surgical intervention for severe trauma, revision knee arthroplasties, and/or Oncology indications.
- 3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

**Device Name:** DCW Modular Distal Femoral System

**Indications:** The DCW Modular Distal Femoral System is primarily indicated for procedures in which a variable resection length prosthesis is necessary to accommodate the condition of the femur, e.g. bone loss/removal in disease-related knee arthroplasty or a distally fractured femur. It is also indicated for revision of a previous total knee replacement where the femoral prosthesis has loosened, broken, or requires surgical removal for another medical reason. These indications are intended to provide relief of pain and restoration of knee function in skeletally mature patients.

**Device Name:** REPIPHYSIS™ Limb Salvage System

**Indications:**

Limb salvage surgery is indicated for cemented procedures where radical resection and replacement of the distal femur and/or proximal tibia is required with the following conditions:

1. patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2. surgical intervention for severe trauma. revision knee arthroplasties, and/or oncology indications.
3. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors)

## **B. Device Description**

The subject devices include the following affected components:

- Tibial spacers manufactured from UHMWPE
- Tibial hinge base with stop pins manufactured from UHMWPE, titanium alloy, and cobalt chromium alloys
- Hinge bushings manufactured from UHMWPE
- Tibial inserts manufactured from UHMWPE with locking screws and posts manufactured from titanium alloy, cobalt chromium tungsten alloy, and cobalt chromium molybdenum alloy
- Femoral axial pins manufactured from combination UHMWPE and cobalt chromium molybdenum alloy and combination high density polyethylene (HDPE) and cobalt chromium alloy
- Yoke extension stops manufactured from UHMWPE

The subject materials conform to the following standards:

- GUR 1050 UHMWPE conforming to ASTM F648
- GUR 1020 UHMWPE conforming to ASTM F648
- High-density polyethylene
- Titanium-6Aluminum-4Vanadium Extra Low Interstitial Alloy conforming to ASTM F136
- Cobalt-28 Chromium-6 Molybdenum Alloy conforming to ASTM F75
- Cobalt-28 Chromium-6 Molybdenum Alloy conforming to ASTM F799

## **C. Substantial Equivalence Information**

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The indications for use and intended patient populations are identical to the predicate devices. The fundamental scientific technology of the subject devices has not changed relative to the predicate devices. The only changes are to ethylene oxide sterilization parameters, and the changes were validated and determined to not have an effect on the safety or effectiveness of the devices.

**D. Nonclinical Testing**

No bench testing, animal testing, or clinical testing was performed to support this submission. The subject sterilization process underwent sterilization validation per standards ISO 11135:2014, ISO/TS 21387, and ISO 10993-7:2008 to demonstrate the new sterilization supplier can sterilize the subject devices to a Sterility Assurance level of  $10^{-6}$ . The sterilization validation shows that the new subject process is capable of achieving the same sterility performance compared to the predicate process. Furthermore, biocompatibility assessment of the subject materials determined material properties and device characteristics are unaffected by the subject modification. The sterilization type and sterility assurance level are not affected by the change and remain identical. The current EO sterilization supplier and the new EO supplier use similar parameters in their EO sterilization cycles, and a comparison of the parameters can be found in the Ethylene Oxide Sterilization Validation Report.

**E. Clinical Testing**

Clinical data were not submitted or relied on for a determination of substantial equivalence.

**F. Biocompatibility**

The subject devices are identical in materials and processing to the predicate devices, with the exception of the subject change. The impact of the subject change on device materials and subsequent biocompatibility of finished devices was assessed, and it was determined that there was no impact to biological safety of implant materials.

**G. Conclusion**

Validations concluded that the ethylene oxide sterilization change in supplier and parameters does not affect the design, safety, or effectiveness of the subject devices. The subject devices are as safe, as effective, and perform the same as the legally marketed predicate devices cited in this 510(k). The indications for use, intended patient population, design features, and fundamental scientific technology of the subject device are identical to the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification submission. Therefore, the subject devices are considered substantially equivalent to the cited predicate devices.

## 510(k) Summary of Safety and Effectiveness

**Submitted by:** MicroPort Orthopedics Inc.  
5677 Airline Rd, Arlington TN, 38002  
USA  
Phone: 866-872-0211  
Fax: 855-446-2247

**Date:** March 29, 2024

**Contact Person:** Ryan Ross, Sr. Manager, Regulatory Affairs

**Proprietary Name:** EVOLUTION® MP Total Knee System  
EVOLUTION® MP Total Knee System  
EVOLUTION® MP Adaptive CS Insert  
EVOLUTION® MP Adaptive PS Tibial Insert  
EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts  
EVOLUTION® Revision CCK System  
ADVANCE® Double High Insert  
ADVANCE® A-CLASS® Tibial Insert  
ADVANCE® Knee System  
ADVANCE® Ultra-Congruent Tibial Insert  
ADVANCED® Revision Product Line Extension  
ADVANCE® Total Knee System-Patella  
ADVANCE® Tibial Component  
Whiteside Condylar II Total Knee Prosthesis  
Whiteside ORTHOLOC™  
Whiteside ORTHOLOC® M.A. Total Knee System  
AXIOM® Total Knee Syst/ACL Retain Tibial Tray/Inser  
AXIOM® Total Knee System, A/P Curved Tibial Insert  
Second GENERATION KNEE SYSTEM  
Whiteside ORTHOLOC® Modular Post. Stab. Knee System  
AXIOM® Total Knee System  
Thick Tibial Insert  
Insall-Burstein II  
ORTHOLOC® ADVANTIM® PS LSI Tibial Insert  
ULTRACK Total Knee System

**Common Name:** Tibial Insert, Total Knee System, Patella, Cementless Femoral Component, Cementless Knee Systems, Cemented Revision Knee Systems, Metal Femoral Component; All Polyethylene Tibial and Patellar Components, Metal-backed Tibial Component, Total Knee Revision Replacement Implant

**Classification Name and Reference:** 21 CFR 888.3565 – Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis  
Class II

**Primary Product Code and Panel Code:** Orthopedics/87/ MBH

**Secondary Product Code:** Orthopedics/87/ JWH, HRY, HSX

**Primary Predicate Device:** **EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts (K140735)**

**Additional Predicates:** **EVOLUTION® MP Total Knee System (K093552)**  
**EVOLUTION® MP Total Knee System (K102380)**  
**EVOLUTION® MP Adaptive CS Insert (K113325)**  
**EVOLUTION® MP Adaptive PS Tibial Insert (K131679)**  
**EVOLUTION® Revision CCK System (K171389)**  
**ADVANCE® Double High Insert (K033890)**  
**ADVANCE® A-CLASS® Tibial Insert (K081479)**  
**ADVANCE® Knee System (K972626)**  
**ADVANCE® Ultra-Congruent Tibial Insert (K972770)**  
**ADVANCED® Revision Product Line Extension (K990030)**  
**ADVANCE® Total Knee System-Patella (K122218)**  
**ADVANCE® Tibial Component (K960617)**  
**Whiteside Condylar II Total Knee Prosthesis (K861715)**  
**Whiteside ORTHOLOC™ (K864070)**  
**Whiteside ORTHOLOC® M.A. Total Knee System (K893252)**  
**AXIOM® Total Knee Syst/ACL Retain Tibial Tray/Inser (K926334)**  
**AXIOM® Total Knee System, A/P Curved Tibial Insert (K912894)**  
**Second GENERATION KNEE SYSTEM (K894334)**  
**Whiteside ORTHOLOC® Modular Post. Stab. Knee System (K901992)**  
**AXIOM® Total Knee System (K932677)**  
**Thick Tibial Insert (K933289)**

**Insall-Burstein II (K935080)**  
**ORTHOLOC® ADVANTIM® PS LSI Tibial Insert (K940235)**  
**ULTRACK Total Knee System (K953439)**

#### **DEVICE INFORMATION**

The purpose of this bundled submission is to notify of a change in ethylene oxide (EO) sterilization supplier taking place, affecting all MicroPort Orthopedics UHMWPE and combination metal/UHMWPE knee system implants. The subject devices consist of multiple devices across multiple systems. The subject devices are identical to the predicate devices in all aspects, and the only change is to the sterilization supplier and sterilization parameters. The subject devices included in this Traditional 510(k) Premarket Notification have been bundled in accordance with “*Bundling Multiple Devices or Multiple Indications in a Single Submission; Guidance for Industry and Food and Drug Administration Staff*” issued on June 22, 2007. Per assessment of the guidance document, MicroPort Orthopedics Inc. has determined the devices bundled in this submission are appropriate as the supporting data are similar, one review division/group is involved, and the devices or indications for use are similar. All subject devices included in this submission are similar devices that undergo the same sterilization process, are affected by the same supplier and parameter changes, and the change is supported by similar validations and assessments.

#### **A. Intended Use/Indications for Use Statement**

**Device Name:** EVOLUTION® MP Total Knee System, EVOLUTION® MP Adaptive CS Insert, EVOLUTION® MP Adaptive PS Tibial Insert, EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts, EVOLUTION® Revision CCK System

**Indications:** The EVOLUTION® MP Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. inflammatory degenerative joint disease including rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Total Knee System nonporous components are for cemented use only.

The EVOLUTION® Total Knee System porous components are for use without bone cement.

**Device Name:** ADVANCE® Double High Insert, ADVANCE® A-CLASS Tibial Insert, ADVANCE® Knee System, ADVANCE® Ultra-Congruent Tibial Insert, ADVANCED® Revision Product Line Extension, ADVANCE® Total Knee System-Patella, ADVANCE® Tibial Component

**Indications:** The ADVANCE® Total Knee System components are indicated for use in total knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 5) treatment of fractures that are unmanageable using other techniques.

The ADVANCE® Total Knee System is for single use. The Advance Total Knee System porous components are for use without bone cement. The Advance Total Knee System non-porous components are for use with bone cement.

**Device Name:** Whiteside Condylar II Total Knee Prosthesis

**Indications:** The Whiteside Condylar II™ Total Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis or inflammatory arthritis or traumatic arthritis, with or without moderate valgus, varus, or flexion deformities. The prosthesis is also indicated for revision of a failed prosthesis where the posterior cruciate and collateral ligaments are intact. The device is intended for cemented use only.

**Device Name:** Whiteside ORTHOLOC

**Indications:** The Whiteside ORTHOLOC™ Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities, where posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. The prosthesis is also indicated for revision of a failed prosthesis where the cruciate ligaments are absent but the collateral ligaments are intact. The device is intended for cemented use only.

**Device Name:** Whiteside ORTHOLOC M.A. Total Knee System

**Indications:** The Whiteside ORTHOLOC® M.A. Total Knee System is indicated for use in conjunction with the metal tibial base of the Whiteside ORTHOLOC® II Total Knee System for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental or tricompartmental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the

posterior cruciate and collateral ligaments are intact. The prosthesis is also indicated for revision of a failed prosthesis where the posterior cruciate and collateral ligaments are intact. The device is intended for cemented use only.

**Device Name:** AXIOM Total Knee Syst/ACL Retain Tibial Tray/Insert

**Indications:** The AXIOM ACL Retaining Tibial Tray and Tibial Insert are used in total knee arthroplasty for replacement of the tibial plateau of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. AXIOM ACL Retaining Tibial Tray and Tibial Insert are for cemented use only.

**Device Name:** AXIOM Total Knee System, A/P Curved Tibial Insert

**Indications:** The A/P Curved Tibial Insert is used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. The A/P Curved Tibial Insert is intended for cemented application only.

**Device Name:** Second Generation Knee System

**Indications:** The Second Generation Knee System is used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. The Second Generation Knee System is intended for cemented application only.

**Device Name:** Whiteside ORTHOLOC Modular Post. Stab. Knee System

**Indications:** The Whiteside ORTHOLOC® Modular Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities, where the posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. This prosthesis is also indicated for revision of a failed prosthesis, where the cruciate ligaments are absent. This device is intended for cemented use only.

**Device Name:** AXIOM Total Knee System

**Indications:** The Modular Femoral Component and Constrained Tibial insert are used in total knee arthroplasty for replacement of the femoral condyles, tibial plateau and patella articulating

surface of the knee joint due to degenerative bone disease, trauma, moderate deformity, or complications from failed prostheses. Additional indications specific to the Modular Femoral Component and Constrained Tibial Insert include use in patients with anterior/posterior, varus/valgus, and rotational joint instability resulting from inadequate or absent cruciate and collateral ligaments, or who's knee can not be stabilized by usual soft tissue management. This device is intended for single use in a cemented application only.

**Device Name:** Thick Tibial Insert

**Indications:** The ORTHOLOC® Tibial Plastic Insert, as part the ORTHOLOC® Total Knee System, is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the posterior cruciate and collateral ligaments are intact. The system is also indicated for revision of failed prosthesis where the posterior cruciate and collateral ligaments are intact. This device is intended for cemented use only.

**Device Name:** Insall-Burstein II

**Indications:** Total knee arthroplasty has been proved effective in reducing or relieving pain and in restoring functional knee motion. Such surgical procedures have been used in the management of: painful disabling bicompartamental joint disease secondary to osteoarthritis, rheumatoid, or traumatic arthritis; posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus or flexion deformities. The device may also be indicated in the salvage of previously failed surgical attempts. This device is intended for cemented use only.

**Device Name:** ORTHOLOC ADVANTIM PS LSI Tibial Insert

**Indications:** The ORTHOLOC® ADVANTIM™ Posterior Stabilized Knee System is indicated for relief of pain and restoration of knee function in skeletally mature patients with bicompartamental or tricompartmental joint disease secondary to osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis, with or without valgus, varus, or flexion deformities where the posterior cruciate ligaments are inadequate, absent or unable to be preserved intraoperatively. This prosthesis is also indicated for revision of a failed prosthesis, where the cruciate ligaments are absent.

**Device Name:** ULTRACK™ Total Knee System

**Indications:** The ULTRACK™ Total Knee System is intended for bicompartamental or tricompartmental replacement of the knee joint for reduction of pain or increased function for the following conditions:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) Inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) Correction of functional deformity;
- 4) Revision procedures where other treatments or devices have failed; and
- 5) Treatment of fractures that are unmanageable using other techniques.

This device is intended for cemented use only.

## **B. Device Description**

The subject devices include the following affected components:

- Tibial inserts manufactured from UHMWPE with locking screws and posts manufactured from titanium alloy, cobalt chromium tungsten alloy, and cobalt chromium molybdenum alloy
- Patellae manufactured from UHMWPE and cobalt chromium tungsten alloy

The subject materials conform to the following standards:

- GUR 1050 UHMWPE conforming to ASTM F648
- GUR 1020 UHMWPE conforming to ASTM F648
- GUR 1020 5 MRad Cross-linked Polyethylene conforming to ASTM F648
- Titanium-6Aluminum-4Vanadium Extra Low Interstitial Alloy conforming to ASTM F136
- Cobalt-28 Chromium-6 Molybdenum Alloy conforming to ASTM F799
- Cobalt-20Chromium-15Tungsten-10Nickel Alloy conforming to ASTM F90

**C. Substantial Equivalence Information**

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The indications for use and intended patient populations are identical to the predicate devices. The fundamental scientific technology of the subject devices has not changed relative to the predicate devices. The only changes are to ethylene oxide sterilization parameters, and the changes were validated and determined to not have an effect on the safety or effectiveness of the devices.

**D. Nonclinical Testing**

No bench testing, animal testing, or clinical testing was performed to support this submission. The subject sterilization process underwent sterilization validation per standards ISO 11135:2014, ISO/TS 21387, and ISO 10993-7:2008 to demonstrate the new sterilization supplier can sterilize the subject devices to a Sterility Assurance level of  $10^{-6}$ . The sterilization validation shows that the new subject process is capable of achieving the same sterility performance compared to the predicate process. Furthermore, biocompatibility assessment of the subject materials determined material properties and device characteristics are unaffected by the subject modification. The sterilization type and sterility assurance level are not affected by the change and remain identical. The current EO sterilization supplier and the new EO supplier use similar parameters in their EO sterilization cycles, and a comparison of the parameters can be found in the Ethylene Oxide Sterilization Validation Report.

**E. Clinical Testing**

Clinical data were not submitted or relied on for a determination of substantial equivalence.

**F. Biocompatibility**

The subject devices are identical in materials and processing to the predicate devices, with the exception of the subject change. The impact of the subject change on device materials and subsequent biocompatibility of finished devices was assessed, and it was determined that there was no impact to biological safety of implant materials.

**G. Conclusion**

Validations concluded that the ethylene oxide sterilization change in supplier and parameters does not affect the design, safety, or effectiveness of the subject devices. The subject devices are as safe, as effective, and perform the same as the legally marketed predicate devices cited in this 510(k). The indications for use, intended patient population, design features, and fundamental scientific technology of the subject device are identical to the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification submission. Therefore, the subject devices are considered substantially equivalent to the cited predicate devices.