May 4, 2023

Smith & Nephew, Inc.
Tyler Kulcsar
Regulatory Affairs Specialist II
1450 East Brooks Rd.
Memphis, Tennessee 38116

Re: K230653

Trade/Device Name: Smith & Nephew, Inc. ANTHEM Total Knee System, Genesis Uni Knee System, JOURNEY BCS and II Knee Systems, JOURNEY II CR Knee System, JOURNEY II Uni Knee System, Journey II UK Knee System, JOURNEY II XR Bi-Cruciate Retaining Knee System, JOURNEY PFJ System, JOURNEY Uni Knee System, Legion Hinge Total Knee System, Legion Total Knee System, ZUK Unicompartmental Knee System, ENGAGE Partial Knee System and Porous Patella and Porous Tibial Baseplates

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, MBH, HSX, KRR, KRO, KWH, OIY

Dated: March 8, 2023

Received: March 9, 2023

Dear Tyler Kulcsar:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -S

Jesse Muir, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
Anthem Total Knee System

Indications for Use *(Describe)*

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The ANTHEM PS Total Knee System is indicated for use only with cement and is a single use device.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
Genesis Uni Knee System

Indications for Use *(Describe)*
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

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

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US 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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510(k) Number *(if known)*

K230653

Device Name
JOURNEY BCS and II Knee Systems

Indications for Use *(Describe)*

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Smith & Nephew, Inc. Journey II BCS Knee components are indicated for use only with cement and are single use devices.

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) Number *(if known)*

K230653

Device Name
JOURNEY II CR Knee System

Indications for Use *(Describe)*

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

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) Number *(if known)*

K230653

Device Name
JOURNEY II Uni Knee System

Indications for Use *(Describe)*
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

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

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US 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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510(k) Number *(if known)*

K230653

Device Name
JOURNEY II UK Knee System

Indications for Use *(Describe)*

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:
• Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed; and
• Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single use only and are intended for implantation only 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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510(k) Number *(if known)*

K230653

Device Name
JOURNEY II XR Bi-Cruciate Retaining Knee System

Indications for Use *(Describe)*
Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

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) Number *(if known)*

K230653

Device Name
JOURNEY PFJ System

Indications for Use *(Describe)*

1. Degenerative arthritis in the distal femur and patella;
2. A history of patellar dislocation or patellar fracture; and
3. Failed previous surgery (arthroplasty, tibial tubercule elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are intended for implantation 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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510(k) Number *(if known)*

K230653

Device Name
JOURNEY Uni Knee System

Indications for Use *(Describe)*
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

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

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US 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

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
Legion Hinge Total Knee System

Indications for Use *(Describe)*

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Legion Hinge Knee System is 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

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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
Legion Total Knee System

Indications for Use *(Describe)*

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The LEGION Knee System - Finned Tibial Wedges are for single use only and are intended for implantation 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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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
ZUK Unicompartmental Knee System

Indications for Use *(Describe)*
These devices are indicated for patients with:

1. Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
2. Previous tibial condyle or plateu fractures with loss of anatomy or function.
3. Varus or Valgus deformities.
4. Revision of previous arthroplasty procedures.

The devices are indicated for cemented use only.

The Zimmer Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

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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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
The Engage™ Partial Knee System

Indications for Use *(Describe)*
The Engage™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty
- As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

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

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See PRA Statement below.

510(k) Number *(if known)*

K230653

Device Name
Porous Patella and Porous Tibia Baseplate

Indications for Use *(Describe)*
Total knee components are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior-stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

LEGION Porous CR Narrow Femoral Components are indicated for use without bone cement and are single use devices.

The Porous Patella and the Porous Tibia Baseplate are indicated for use with or without bone cement, and are single use devices.

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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

Submitted by:

Smith & Nephew, Inc. Orthopaedic Division
7135 Goodlett Farms Parkway Cordova,
Tennessee 38016

Date of Submission:

March 8, 2023

Contact Person:

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Senior Manager Regulatory Affairs
Rose.Beifuss@smith-nephew.com
Mobile: (385)-253-2551

Name of Device:

Smith & Nephew, Inc. ANTHEM Total Knee System, Genesis Uni Knee System, JOURNEY BCS and II Knee Systems, JOURNEY II CR Knee System, JOURNEY II Uni Knee System, Journey II UK Knee System, JOURNEY II XR Bi-Cruciate Retaining Knee System, JOURNEY PFJ System, JOURNEY Uni Knee System, Legion Hinge Total Knee System, Legion Total Knee System, ZUK Unicompartmental Knee System, ENGAGE Partial Knee System and Porous Patella and Porous Tibial Baseplates

Common Name:

Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Device Classification Name and Reference:	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis 21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis 21 CFR 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis 21 CFR 888.3720 Toe joint polymer constrained prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH, HSX, KRR, KRO, KWH, OIY
Predicate Device:	ANTHEM Total Knee System, Genesis Uni Knee System, JOURNEY BCS and II Knee Systems, JOURNEY II CR Knee System, JOURNEY II Uni Knee System, JOURNEY II UK Knee System JOURNEY II XR Bi-Cruciate Retaining Knee System, JOURNEY PFJ System, JOURNEY Uni Knee System, Legion Hinge Total Knee System, Legion Total Knee System, ZUK Unicompartmental Knee System, ENGAGE Partial Knee System and Porous Patella and Porous Tibial Baseplates

Device Description:

The purpose of this Traditional 510(k) is to add MR safety information to the labeling (instructions for use, product labeling and patient implant card) of the subject Smith & Nephew Knee Systems. The technological characteristics, function of the devices, packaging and sterilization remain unchanged. As these products have been in distribution for several years, some parts have undergone changes in the technological characteristics that were assessed in compliance with the FDA's guidanceon "Deciding When to Submit a 510(k) for a Change to an Existing Device" or the FDA predecessor guidance on how to review changes to an existing device. These are not cumulative changes for all Smith & Nephew Knee Systems, but are rather specific changes that only affect certain parts. In the context of this submission, no modifications have been made to the device design, materials, sterilization, or the manufacturing process of the previously cleared devices due to the addition of MR Labeling for this 510(k).

Indications for Use

Legion Hinge

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Legion Hinge Knee System is for Cemented Use Only.

Legion

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent.
6. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The LEGION Knee System - Finned Tibial Wedges are for single use only and are intended for implantation with bone cement.

Journey BCS and Journey II

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Smith & Nephew, Inc. Journey II BCS Knee components are indicated for use only with cement and are single use devices.

Anthem Total Knee System

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The ANTHEM PS Total Knee System is indicated for use only with cement and is a single use device.

Journey II CR Knee System

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

Unicompartmental Knee Systems
Genesis Uni, Journey II Uni, Journey II UK, Journey Uni

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

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

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US for use without bone cement.

Journey Patello-Femoral Replacement System

1. Degenerative arthritis in the distal femur and patella;
2. A history of patellar dislocation or patellar fracture; and
3. Failed previous surgery (arthroplasty, tibial tubercule elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are intended for implantation with bone cement.

Journey II XR Bi-Cruciate Retaining Knee System

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement,or total knee replacement.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

ZUK Unicompartmental Knee System

These devices are indicated for patients with:

1. Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
2. Previous tibial condyle or plateu fractures with loss of anatomy or function.
3. Varus or Valgus deformities.
4. Revision of previous arthroplasty procedures.

The devices are indicated for cemented use only.

The Zimmer Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Engage™ Partial Knee System

The Engage™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

1. Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
2. Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty
3. As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

Porous Patella and Porous Tibial Baseplates

Total Knee components are indicated for:

1. Rheumatoid arthritis
2. Post- traumatic arthritis, osteoarthritis, or degenerative arthritis
3. Failed osteotomies, unicompartmental replacement, or total knee replacement
4. The posterior stabilized knee system is designed for use in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

LEGION POROUS CR Narrow Femoral Components are indicated for use without bone cement and are single use devices.

The Porous Patella and the Porous Tibia Baseplate are indicated for use with or without bone cement, and are single use devices.

Technological Characteristics

The device design and material of the subject devices are the same as the predicate Smith & Nephew Knee Systems, including substantially equivalent letter to file cleared under the premarket notifications listed in **Table 6.1**.

Performance Data

Below listed Magnetic Resonance Imaging (MRI) compatibility testing was conducted asper the FDA's guidance and the standards listed below .

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213)
3. Radiofrequency (RF) induced heating (ASTM F2182-19e2, IEC 60601-2-33, ISO/TS 10974:2018E)
4. MR image artifact (ASTM F2119)

MR Safety testing/ assessments support the appropriate MR parameters and symbols found in the subject device labeling.

As these products have been in distribution for several years, bacterial endotoxin testing was completed in previous submissions. The addition of the MR safety information to thelabeling does not affect the pyrogenicity, therefore, the subject Smith & Knee Systems are still expected to met the acceptable endotoxin limits as stated in the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72.

Substantial Equivalence Information

The subject Smith & Nephew Knee Systems are identical in design, technological characteristics, function of the devices, packaging and sterilization to the commercially available predicate devices, including substantially equivalent letter to file parts, listed in **Table 6.1** below.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew,Inc.	ANTHEM Total Knee System	K142807 K170648	12/22/2014 05/11/2017
Smith & Nephew,Inc.	Genesis Uni Knee System	K030301 K912735	02/25/2003 12/27/1991
Smith & Nephew,Inc.	JOURNEY BCS and II Knee Systems	K042515 K111711 K140555	03/14/2005 09/16/2011 05/29/2014
Smith & Nephew,Inc.	JOURNEY II CR Knee System	K113482 K121443	02/27/2012 08/13/2012
Smith & Nephew,Inc.	JOURNEY II Uni Knee System	K152315	10/28/2015
Smith & Nephew, Inc.	JOURNEY II UK Knee System	K190085	2/11/2019
Smith & Nephew,Inc.	JOURNEY II XR Bi-Cruciate Retaining Knee System	K152726	10/21/2015
Smith & Nephew,Inc.	JOURNEY PFJ System	K051086	05/31/2005
Smith & Nephew,Inc.	JOURNEY Uni Knee System	K061011 K061779 K073175 K102069	07/11/2006 08/04/2006 12/20/2007 10/05/2010
Smith & Nephew, Inc.	Legion Hinge Total Knee System	K151118 K081111	07/28/2015 07/23/2008

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew,Inc.	Legion Total Knee System	K041106 K043440 K060742 K071071 K072531 K073325 K091543 K100897 K112941 K162775 K180334	07/01/2004 02/18/2005 05/03/2006 09/19/2007 12/06/2007 12/20/2007 12/21/2009 05/13/2010 12/20/2011 01/13/2017 03/05/2018
Smith & Nephew,Inc.	ZUK Unicompartmental Knee System	K033363 K122529	01/16/2004 11/16/2012
Smith & Nephew, Inc.	ENGAGE Partial Knee System	K190439	11/21/2019
Smith & Nephew, Inc.	Porous Patella and Porous Tibial Baseplates	K211221	10/01/2021

Conclusion

In summary, the only differences between the subject devices, including substantially equivalent letter to file catalog items and the commercially available predicate devices were supporting MR safety testing/assessment and the addition of MR safety information to the labeling. These differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the subject devices. The subject Smith & Nephew Knee Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared and do not affect the safety and effectiveness of the subject devices when used as labeled. Due to the supporting documentation within this filing, it is conducted that the subject device(s) are substantially equivalent to the predicate device(s).