Smith & Nephew, Inc.
Michelle Huettner
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

November 14, 2022

Re: K210980
Trade/Device Name: Smith & Nephew Intramedullary Nail Systems
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: November 8, 2022
Received: November 8, 2022

Dear Michelle Huettner:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2022.11.14 16:17:30 -05'00'

For Victoria Lilling, M.D.
Assistant Division 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)*
K210980

Device Name
Trigen Antegrade Tibial/Retrograde Femoral Nailing System

Indications for Use *(Describe)*
Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (periprosthetic fractures).

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210980

Device Name
Trigen Tan/Fan Nailing System

Indications for Use *(Describe)*
Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/ neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and SupracondylarNails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

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

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

510(k) Number *(if known)*
K210980

Device Name
Trigen Hindfoot Fusion Nail System

Indications for Use *(Describe)*
Indications for the TRIGEN Hindfoot Fusion Nail (HFN) include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations of the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the sub-talar joint.

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
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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210980

Device Name
Trigen Humeral Nail System

Indications for Use *(Describe)*
The TRIGEN Humeral Nail System is indicated for proximal and/or diaphyseal fractures of the humerus, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

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
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210980

Device Name
Trigen Intertan Intertrochanteric Antegrade Nail System

Indications for Use *(Describe)*
The TRIGEN InterTAN nails are indicated for simple long bone fractures; severely comminuted, spiral, long oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening; subtrochanteric fractures; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; and intracapsular fractures.

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210980

Device Name
Trigen Knee Fusion Nail System

Indications for Use *(Describe)*
Knee Fusion Nails are intended for intramedullary knee arthrodesis.

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:	**November 7, 2022**
Contact Person:	Senior Manager, Regulatory Affairs Email: Rose.Beifuss@smith-nephew.com Phone: (385) 253-2551
Name of Device:	Smith & Nephew Intramedullary Nail Systems • Trigen Antegrade Tibial/Retrograde Femoral Nailing System • Trigen Tan/Fan Nailing System • Trigen Hindfoot Fusion Nail System • Trigen Humeral Nail System • Trigen Intertan Intertrochanteric Antegrade Nail System • Trigen Knee Fusion Nail System
Common Name:	Intramedullary Nails
Device Classification Name and Reference:	21 CFR 888.3020 – Intramedullary fixation rod with corresponding Product Code HSB

	21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories with corresponding Product Codes JDS
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSB – Intramedullary fixation rod JDS – Single/multiple component metallic bone fixation appliances and accessories
Predicate Device:	Smith & Nephew Intramedullary Nail Systems • Trigen Antegrade Tibial/Retrograde Femoral Nailing System (K981529 S.E. 7/9/1998, K051557 S.E. 6/30/2005 and K061019 S.E. 6/6/2006) • Trigen Tan/Fan Nailing System (K981529 S.E. 7/9/1998 K040929 S.E.5/25/2004, and K111025 S.E. 7/1/2011) • Trigen Hindfoot Fusion Nail System (K043052 S.E. 11/24/2004) • Trigen Humeral Nail System (K032722 S.E. 10/1/2003) • Trigen Intertan Intertrochanteric Antegrade Nail System (K040212 S.E. 2/20/2004) • Trigen Knee Fusion Nail System (K050938 S.E. 5/4/2005)

Device Description:

The purpose of this Traditional 510(k) is to add the MR safety information to the labeling and update the information within the package insert for the Smith & Nephew Intramedullary Nail Systems. The Smith & Nephew Intramedullary Nail Systems consist of the following previously cleared devices:

- Trigen Antegrade Tibial/Retrograde Femoral Nailing System (K981529 S.E. 7/9/1998, K051557 S.E. 6/30/2005 and K061019 S.E. 6/6/2006)
    - The Trigen Antegrade Tibial/Retrograde Femoral Nailing System includes retrograde femoral, supercondylar, and tibial intramedullary nails, and nail cap. All described components are manufactured from titanium material.
- Trigen Tan/Fan Nailing System (K981529 S.E. 7/9/1998, ,K040929 S.E. 5/25/2004, and K111025 S.E. 7/1/2011)
    - The Trigen Tan/Fan Nailing System includes trochanteric antegrade nails and femoral antegrade nails, femoral and tibial nails and low profile bone screws. All components are manufactured from titanium alloy.
- Trigen Hindfoot Fusion Nail System (K043052 S.E. 11/24/2004)
    - The Trigen Hindfoot Fusion Nail System includes right and left nail designs in 10 mm and 11.5 mm with nail lengths ranging from 16-25 cm.
- Trigen Humeral Nail System (K032722 S.E. 10/1/2003)
    - The Trigen Humeral Nail System includes both a proximal fracture nail (8 mm diameter and 16 cm length) and a shaft fracture nail (8 to 10 mm diameter and 18 to 28 cm lengths) with features of a diverging proximal screw hole pattern for better stability. All components are made of titanium material.
- Trigen Intertan Intertrochanteric Antegrade Nail System (K040212 S.E. 2/20/2004)
    - The Trigen Intertan Intertrochanteric Antegrade Nail System includes right and left nail designs as well as a universal nail which can be used for both left or right side fracture. All described nails are manufactured from titanium material.
- Trigen Knee Fusion Nail System (K050938 S.E. 5/4/2005)

- The Trigen Knee Fusion Nail System includes intramedullary interlocking nails with corresponding screws. All components are made of titanium material.

The technological characteristics, function of the devices, packaging and sterilization remain unchanged. No modifications have been made to the device design, material, sterilization and the manufacturing processes of the previously cleared devices as a part of this subject 510(k).

Indications for Use

Trigen Antegrade Tibial/Retrograde Femoral Nailing System

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (periprosthetic fractures).

Trigen Tan/Fan Nailing System

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/ neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

Trigen Hindfoot Fusion Nail System

Indications for the TRIGEN Hindfoot Fusion Nail (HFN) include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations of the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the sub-talar joint.

Trigen Humeral Nail System

The TRIGEN Humeral Nail System is indicated for proximal and/or diaphyseal fractures of the humerus, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

Trigen Intertan Intertrochanteric Antegrade Nail System

The TRIGEN InterTAN nails are indicated for simple long bone fractures; severely comminuted, spiral, long oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening; subtrochanteric fractures; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; and intracapsular fractures.

Trigen Knee Fusion Nail System

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

Technological Characteristics

The overall device design and material of the subject devices are the same as the predicate Smith & Nephew Intramedullary Nail Systems cleared under the premarket notifications listed in **Table 5.1**.

Substantial Equivalence Information

The Smith & Nephew Intramedullary Nail Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices listed in **Table 5.1** below.

Table 5.1: Substantially Equivalent Predicates to the Intramedullary Nail Systems

Manufacturer	Description	Submission Number	Clearance Date	Product Code
Smith & Nephew	Trigen Antegrade Tibial/Retrograde Femoral Nailing System	K981529 K051557 K061019	7/9/1998 6/30/2005 6/6/2006	JDS
Smith & Nephew	Trigen Hindfoot Fusion Nail System	K043052	11/24/2004	HSB
Smith & Nephew	Trigen Tan/Fan Nailing System	K981529K040929K111025	7/9/1998 5/25/2004 7/1/2011	JDS HSB
Smith & Nephew	Trigen Humeral Nail System	K032722	10/1/2003	HSB
Smith & Nephew	Trigen Intertan Intertrochanteric Antegrade Nail System	K040212	2/20/2004	JDS
Smith & Nephew	Trigen Knee Fusion Nail System	K050938	5/4/2005	JDS

Performance Data

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

1. FDA Guidance Document: "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Guidance for Industry and Food and Drug Administration Staff", 20 May 2021.

2. Reporting of Computational Modeling Studies in Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff, September 21, 2016

3. IEC 60601-2-33 (Ed 3.2), "Medical electrical equipment –Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis" (2015).

4. ASTM F2182-19e2, "Standard Test Method for Measurement of Radio Frequency

5. Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging" (2020).

6. ISO/TS 10974:2018(E) "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device".

7. ASTM F2052-15 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.

8. ASTM F2213-2017 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

9. ASTM F2182-19 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging

10. ASTM F2119-07 (2013) - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Conclusion

In summary, the only differences between the subject devices 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 use of the subject devices and do not change the indications for use. Due to the supporting testing and evidence within this filing, it is concluded that the Smith & Nephew Intramedullary Nail Systems are substantially equivalent to the predicate devices.