Smith & Nephew, Inc.
Kayla Franklin
Regulatory Approval Representative 2
1450 Brooks Rd
Memphis, Tennessee 38116

September 20, 2024

Re: K240061
Trade/Device Name: TRIGEN MAX Tibial Nail System; INTERTAN MAX Hip Fracture Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDS, HSB, HRS, HWC
Dated: August 21, 2024
Received: August 21, 2024

Dear Kayla Franklin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.09.20 09:45:15 -04'00'

for: Farzana Sharmin, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K240061

Device Name

TRIGEN MAX Tibial Nail System;
INTERTAN MAX Hip Fracture Nail System

Indications for Use *(Describe)*

TRIGEN MAX Tibial Nail System:
The TRIGEN MAX Tibial Nail is indicated for stable and unstable fractures that occur in and between the proximal and distal third of the tibia, including the shaft.

INTERTAN MAX Hip Fracture Nail System:
The INTERTAN MAX Nails are indicated for fractures of the femur including:
• Fractures of the femur including simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, and segmental shaft fracture; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures
• Polytrauma and multiple fractures
• Prophylactic nailing of impending pathologic fractures
• Reconstruction following tumor resection and grafting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K240061

510(k) Summary

Prepared on: 2024-09-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 Brooks Rd Memphis TN 38116 United States
Applicant Contact Telephone	9013252471
Applicant Contact	Ms. Kayla Franklin
Applicant Contact Email	kayla.franklin@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TRIGEN MAX Tibial Nail System; INTERTAN MAX Hip Fracture Nail System
Common Name	Nail, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	888.3030
Product Code(s)	JDS, HSB, HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K061019	TRIGEN META-NAIL RETROGRADE FEMORAL AND TIBIAL N/	JDS
K040212	TRIGEN INTERTAN	JDS

Device Description Summary

21 CFR 807.92(a)(4)

The Smith & Nephew TRIGEN MAX Tibial Nail and INTERTAN MAX Hip Fracture Nail systems consist of implant intramedullary nails, screws, nail caps, buttress plate, washers and their corresponding US Class II instrumentation. The TRIGEN MAX Tibial Nail system is designed to address fractures of the tibia and the INTERTAN MAX Hip Fracture Nail system is designed to address fractures of the proximal femur.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

TRIGEN MAX Tibial Nail System:
The TRIGEN MAX Tibial Nail is indicated for stable and unstable fractures that occur in and between the proximal and distal third of the tibia, including the shaft.

INTERTAN MAX Hip Fracture Nail System:
The INTERTAN MAX Nails are indicated for fractures of the femur including:
- Fractures of the femur including simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, and segmental shaft fracture; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures
- Polytrauma and multiple fractures
- Prophylactic nailing of impending pathologic fractures
- Reconstruction following tumor resection and grafting.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject devices fall within the indications cleared for the predicates.

Technological Comparison 21 CFR 807.92(a)(6)

The overall technological characteristics including device design and material of the subject devices are similar to that of the primary predicate Smith & Nephew systems cleared under the premarket notifications TRIGEN META-NAIL Tibial Nail (K061019, S.E. 06/06/06) and TRIGEN INTERTAN (K040212, S.E. 02/20/04). The subject devices, including the nailing system accessories, are also technologically similar to the reference devices DePuy Synthes Femoral recon Nail System (K172157, S.E. 11/14/17), TRIGEN Low Profile Screw (K111025, S.E. 07/01/11; K161264, S.E. 11/23/16), Titanium Intramedullary Nail, Titanium locking Screw (K981529, S.E. 07/09/98), Smith & Nephew Bone Plate System (Bone Plates, Bone Screw and Accessories) (K993106, S.E. 12/09/99), and EVOS Small Fragment Plating System (K162078, S.E. 11/18/16).

As result, all relevant testing makes references to existing information previously provided to the agency.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

- Finite Element Analysis (FEA)
- Insertion and Removal Torque per ASTM F543-17
- Torque to Failure per ASTM F543-23 and ISO 6475
- Bending Fatigue per ASTM F1264-16e1, ASTM F543-23, and ASTM F382-17
- Cantilever Bending Fatigue per ASTM F1264
- Cantilever Bending Evaluation per ASTM F543-23
- Proximal Shaft Fracture Construct Fatigue Testing
- Bending Strength Evaluation per ASTM F1264-16e1
- Bending and Torsional Stiffness Evaluation per ASTM F1264-16e1
- Dual Locking Ridge-Axial Stability per ASTM F1264-16e1
- Insertion/Axial Pullout per ASTM F543-23
- MR Compatibility (implants only) per ASTM F2182-19e2, ASTM F2052-15, ASTM F2213-2017, and ASTM F2119-07(2013)
- Biocompatibility per ISO 10993-1

No clinical tests were performed to support safety and efficacy of the subject devices.

The performance bench evaluations and tests were used as a basis for the determination of substantial equivalence. The results of each evaluation or test show that when compared to the predicate devices, the subject devices have demonstrated substantially equivalent performance.