Smith & Nephew Inc.
Hiral Rathod
Sr. Regulatory Affairs Specialist
1450 Brooks Rd
Memphis, Tennessee 38116

August 22, 2024

Re: K241804
Trade/Device Name: TRIGEN INTERTAN 10S 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
Dated: June 19, 2024
Received: June 21, 2024

Dear Hiral Rathod:

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) 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: 2024.08.22 16:48:52 -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)*

K241804

Device Name

TRIGEN INTERTAN 10S Nail System

Indications for Use *(Describe)*

The TRIGEN INTERTAN 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 fractures; 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.**

# 510(k) Summary

Prepared on: 2024-08-22

## 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 | 901-205-4852 |
| Applicant Contact | Ms. Hiral Rathod |
| Applicant Contact Email | hiral.rathod@smith-nephew.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | TRIGEN INTERTAN 10S 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 |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K040212 | TRIGEN INTERTAN | JDS |
| K040462 | TRIGEN TROCHANTERIC ANTEGRADE NAIL | HSB |

## Device Description Summary

21 CFR 807.92(a)(4)

The TRIGEN INTERTAN 10S Nail System consists of metallic implants including femur nails, leg screw, compression screw, Subtrochanteric lag screw, locking screw, Set Screw, and nail caps.

TRIGEN INTERTAN 10S nail is designed to have a slightly different neck taper from the existing neck design of the predicate TRIGEN INTERTAN 10mm Nail (K040212, SE 02/20/2004). The neck taper of the subject devices has been modified to accommodate the different patient population.

The TRIGEN INTERTAN 10S system is intended to provide a solution for treatment of proximal femoral fractures with one nail product. The INTERTAN nail includes two interlocking screws near the proximal end that form a worm gear, which is designed to provide stability for hip fracture cases.

The subject TRIGEN INTERTAN 10S nails are made of Titanium-6 Aluminum-4 Vanadium (Ti-6Al-4V). The 10S nails are available in both long and short nails. The "S" stands for small since they are the smallest diameter nails offered. Design wise, the only difference is the small diameter and a change to the neck taper. The subject INTERTAN 10S Nail implants are available in the 10mm diameter size, with lengths from 18cm to 46cm in 2cm increments, in both 125° or 130° neck angle versions. The INTERTAN 10S nails are single-use and are Gamma sterilized.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TRIGEN INTERTAN 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 fractures; 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 subject device indications are identical to the predicate indications for use.

## Technological Comparison 21 CFR 807.92(a)(6)

The subject devices have a different neck taper geometry then the predicate device. The subject INTERTAN 10S nail has a modified, steeper neck taper vs predicate INTERTAN 10mm where the design transitions from a larger, proximal end, to the smaller, distal end diameter.

The overall technological characteristic including device design, material, packaging, and sterilization of the subject devices are similar to that of the predicate Smith & Nephew systems cleared under the premarket notifications TRIGEN INTERTAN (K040212, S.E. 02/20/04) and TRGEN TAN (K040462, 03/23/2004).

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

- Proximal Shaft Fracture Construct Fatigue Testing
- MR Compatibility per ASTM F2182-19e2, ASTM F2052-15, ASTM F2213-2017, and ASTM F2119-07(2013)

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

The performance bench tests were used as a basis for the determination of substantial equivalence. The results of equivalence testing demonstrate acceptable outcomes. The results of these tests show that the subject device is substantially equivalent to the predicate device.