June 12, 2025

Smith & Nephew, Inc.
Jessica Roach
Regulatory Affairs Specialist II
1450 E Brooks Road
Memphis, Tennessee 38116

Re: K243608
Trade/Device Name: TRIGEN Stable Lock Nut & Washer
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: May 20, 2025
Received: May 20, 2025

Dear Jessica Roach:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.06.12 11:45:02 -04'00'

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)*

K243608

Device Name

TRIGEN Stable Lock Nut & Washer

Indications for Use *(Describe)*

The subject device can be used with the TRIGEN META-TAN Trochanteric Antegrade Nailing System, TRIGEN TAN FAN Trochanteric Antegrade and Femoral Antegrade Nailing System, and the TRIGEN META-NAIL Retrograde Femoral Nail System therefore the indications for use for all three systems are applicable to the subject TRIGEN Stable Lock Nut & Washer.

TRIGEN META-TAN Trochanteric Antegrade Nailing System

The TRIGEN META-TAN Trochanteric Antegrade Nail is indicated for fixation of fractures that occur in and between the proximal third and distal fourth of the femur including simple long bone fractures, severely comminuted, spiral, and segmental fractures, and supracondylar fractures.

In addition, TRIGEN META-TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; and intracapsular fractures.

TRIGEN TAN FAN Trochanteric Antegrade and Femoral Antegrade Nailing System

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted spiral, large oblique and segmental fractures; and nonunions. 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 and intertrochanteric fractures.

TRIGEN META-NAIL Retrograde Femoral Nail System

The TRIGEN META-NAIL Retrograde Femoral Nail is indicated for fractures of the femur including stable and unstable distal metaphyseal fractures, diaphyseal fractures, intra-articular fractures, and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) #: K243608

510(k) Summary

Prepared on: 2025-06-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 E Brooks Road Memphis TN 38116 United States
Applicant Contact Telephone	978-474-6318
Applicant Contact	Ms. Jessica Roach
Applicant Contact Email	jessica.roach@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TRIGEN Stable Lock Nut & Washer
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Nail, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	JDS, HSB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K983942	Stainless-Steel Stable Lock Nut & Washer	JDS
K111025	TRIGEN Low Profile Screw	HSB
K061019, K230761	TRIGEN META-NAIL Retrograde Femoral Nail	JDS
K243364	TRIGEN META-TAN Trochanteric Antegrade Nail	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The device in scope of this submission is the TRIGEN Stable Lock Nut & Washer.

The TRIGEN Stable Lock Nut & Washer is intended to be used as an aid to normal fracture healing for fractures that occur in and between the proximal third and distal fourth of the femur including simple long bone fractures, severely comminuted, spiral, and segmental fractures, and supracondylar fractures; simple long bone fractures; severely comminuted spiral, large oblique and segmental fractures; nonunions; for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated; and for fractures of the femur that include stable and unstable distal metaphyseal fractures, diaphyseal fractures, intra-articular fractures, and peri-prosthetic fractures . The TRIGEN Stable Lock Nut & Washer is made from Ti-6Al-4V material. The device is Gamma sterilized and intended for single-use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The subject device can be used with the TRIGEN META-TAN Trochanteric Antegrade Nailing System, TRIGEN TAN FAN Trochanteric Antegrade and Femoral Antegrade Nailing System, and the TRIGEN META-NAIL Retrograde Femoral Nail System therefore the

Indications for use for all three systems are applicable to the subject TRIGEN Stable Lock Nut & Washer.

TRIGEN META-TAN Trochanteric Antegrade Nailing System

The TRIGEN META-TAN Trochanteric Antegrade Nail is indicated for fixation of fractures that occur in and between the proximal third and distal fourth of the femur including simple long bone fractures, severely comminuted, spiral, and segmental fractures, and supracondylar fractures.

In addition, TRIGEN META-TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; and intracapsular fractures.

TRIGEN TAN FAN Trochanteric Antegrade and Femoral Antegrade Nailing System

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted spiral, large oblique and segmental fractures; and nonunions. 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 and intertrochanteric fractures.

TRIGEN META-NAIL Retrograde Femoral Nail System

The TRIGEN META-NAIL Retrograde Femoral Nail is indicated for fractures of the femur including stable and unstable distal metaphyseal fractures, diaphyseal fractures, intra-articular fractures, and peri-prosthetic fractures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject TRIGEN Stable Lock Nut & Washer indications fall within the predicate devices' indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

The overall device design is similar to that of the predicate Smith & Nephew system cleared under the premarket notification Stainless-Steel Stable Lock Nut & Washer (K983942, SE 12/04/1998) except for the device material, and threads. The subject device material and threads are similar to that of the predicate Smith & Nephew system cleared under the premarket notification TRIGEN Low Profile Screw (K111025, SE 07/01/2011).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

- Theoretical Failure Analysis
- Torque to Failure/Insertion/Extraction Torque Testing and Analysis
- 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 the equivalence testing demonstrate that the differences in design of the subject device does not raise any difference in safety or effectiveness as compared to the predicate devices.