June 14, 2023

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

Re: K230761
Trade/Device Name: TRIGEN META-NAIL 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
Dated: March 17, 2023
Received: March 20, 2023

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 (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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.06.14 17:42:15 -04'00'

For: Farzana Sharmin, 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)*
K230761

Device Name
TRIGEN META-NAIL Nail System

Indications for Use *(Describe)*
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.

The TRIGEN META-NAIL Antegrade Tibial Nail is indicated for stable and unstable fractures of the proximal and distal third of the tibia, including the shaft.

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.

510k Summary

Contact Detail	**21 CFR 807.92(a)(1)**
Applicant name	Smith & Nephew Inc.
Applicant Address	1450 Brooks Rd E 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 META-NAIL Nail System
Common Name	Nail, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	888.3030
Product Code	JDS

Legally Marketed Predicate Devices **21 CFR 807.92(a)(3)**

Predicate #	**Predicate Trade Name (Primary Predicate is listed first)**	**Product Code**
K051557	TRIGEN Retrograde Femoral, Supracondylar And Tibial Nails	JDS
K061019	TRIGEN Meta-Nail Retrograde Femoral And Tibial Nails	JDS
K981529	Titanium Intramedullary Nail, Titanium Locking Screw	JDS

Device Description Summary **21 CFR 807.92(a)(4)**

The purpose of this traditional 510K is notifying FDA of Smith & Nephew's intent to request clearance for labeling updates which include indication updates in IFU/Package Insert to Smith & Nephew's TRIGEN META-NAIL Nail Systems. There are no significant changes in design, technological characteristics, function, sterilization and packaging of the devices, as a result of this submission. The TRIGEN META-NAIL Nail Systems is designed to be used for internal fixation of long bones in skeletally mature patients.

The Subject TRIGEN META-NAIL Systems include TRIGEN Retrograde Femoral, Supracondylar and Tibial Nails (K051557, 6/30/2005), TRIGEN Meta-Nail Retrograde Femoral and Tibial Nails and TRIGEN META-NAIL Nail Cap Set Screw (K061019, 6/6/2006).

The subject Smith & Nephew TRIGEN META-NAIL Systems devices are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared. These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

The TRIGEN META Antegrade Tibial Nails and the TRIGEN META Retrograde Femoral Nails are intended for the internal fixation of long bones in skeletally mature patients.

The TRIGEN META Antegrade Tibial Nails and the TRIGEN META Retrograde Femoral Nails have a round, cannulated geometry and are composed of biocompatible implantable titanium alloy (Ti-6Al-4V complied to ASTM F1472/ISO 5832-3). The TRIGEN META-NAIL Antegrade Tibial Nail & Retrograde Femoral Nails are provided preassembled with polyethylene sleeves, which are manufactured from ultra-high molecular weight polyethylene (UHMWPE)] conforming to ASTM F648 and ISO 5834-2. The TRIGEN META Antegrade Tibial Retrograde Femoral Nailing System also include nail cap set screws. The

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META Nail Cap Set Screw is also composed of the same Titanium alloy (TI-6Al-4V) as the nail implants. This material is identical to material that has been in previous Smith&Nephew Intramedullary nail system submission including the predicate TRIGEN Retrograde Femoral, Supracondylar and Tibial Nails (K051557, 6/30/2005), TRIGEN Meta-Nail Retrograde Femoral and Tibial Nails (K061019, 6/6/2006), and Titanium Intramedullary Nail, Titanium Locking Screw (K981529, 7/9/1998). These implants are design to provide a solution for fracture fixation and are offered in a variety of diameters (8.5-13mm) and lengths (16-50cm).
The implants within this system are single-use and are Gamma sterilized.

Intended Use/Indications for Use **21 CFR 807.92(a)(5)**

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.

The TRIGEN META-NAIL Antegrade Tibial Nail is indicated for stable and unstable fractures of the proximal and distal third of the tibia, including the shaft.

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

The purpose of this Traditional 510K is to notify FDA of our intent to request clearance for changes to Smith & Nephew's TRIGEN META-NAIL Nail System labeling which include updated indications.
The Indications provided in the Predicate 510ks were for overall Intramedullary nail system which were not all applicable to the Subject TRIGEN META-NAIL Nail System. Indication updates include removal of non-applicable Indications. Additionally, the indication verbiage is updated to clearly state the specific long bones the nails are used in and are more focused on the location of the fracture; Retrograde Femoral Nails are used in the femur; Tibial Nails are used in the tibia; which does not constitute a new intended use.

The Smith & Nephew TRIGEN META-NAIL Nail Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices TRIGEN Retrograde Femoral, Supracondylar and Tibial Nails (K051557, 6/30/2005) and TRIGEN Meta-Nail Retrograde Femoral and Tibial Nails (K061019, 6/6/2006) and Titanium Intramedullary Nail, Titanium Locking Screw (K981529, 7/9/1998).

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

The overall technological characteristic including device design and material of the subject devices are the same as the predicate Smith & Nephew, Inc. Nailing system cleared under the premarket notifications TRIGEN Retrograde Femoral, Supracondylar and Tibial Nails (K051557, 6/30/2005), TRIGEN Meta-Nail Retrograde Femoral and Tibial Nails (K061019, 6/6/2006), and Titanium Intramedullary Nail, Titanium Locking Screw (K981529, 7/9/1998).
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)**

The purpose of this traditional 510(k) is to request clearance from FDA for labeling changes to the subject Smith & Nephew TRIGEN META-NAIL Nail System implants.

The subject Smith & Nephew TRIGEN META-NAIL Nail System devices are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was

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previously 510(k) cleared. These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

Therefore, since there are no changes to the design features, materials, or manufacturing methods of the subject TRIGEN META-NAIL Nail System devices, no performance testing (bench, animal, clinical) was required.

No modifications are being introduced to the subject devices as a result of this filing. The subject devices are substantially equivalent to the previously 510(k) cleared predicate devices.