DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 23, 2016

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

Re: K161264
Trade/Device Name: TRIGEN Low Profile Bone Screws
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 27, 2016
Received: October 28, 2016

Dear Allison Chan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161264

Device Name
TRIGEN Low Profile Bone Screws

Indications for Use *(Describe)*

The TRIGEN™ Low Profile Bone Screw can be used with several types of nails in Smith & Nephew's (TRIGEN™) Titanium Nail System. The TRIGEN™ Low Profile Bone Screw therefore has the following indications:

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).

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

META-TAN™ Nails are indicated for fractures of the femur including 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; and for fixation of fractures that occur in and between the proximal third and distal fourth of the femur.

In addition, META-TAN™ 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; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

The TRIGEN™ Low Profile Bone Screw is intended for single use only.

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.

PSC Publishing Services (301) 443-6740 EF

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 27, 2016
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist II T 901-399-1098 F 901-566-7022
Name of Device:	Smith & Nephew, Inc. TRIGEN™ Low Profile Bone Screws
Common Name:	Bone Screw
Device Classification Name and Reference:	21 CFR 888.3020 Intramedullary Fixation Rod
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSB

Device Description
The subject of this Special 510(k) Premarket Notification is the 5.0mm TRIGEN™ Low Profile Bone Screws. Specifically, subject devices are modified with a change in the tip. All described implant devices are manufactured from implant grade titanium alloy material (Ti-Al-4V) and designed for single use. The subject devices are provided in a sterile packaged option and will be sterilized via Gamma irradiation.

The subject devices are designed to be used with TRIGEN™ Titanium intramedullary nail systems.

Intended Use
The TRIGEN™ Low Profile Bone Screw can be used with several types of nails in Smith & Nephew's (TRIGEN™) Titanium Nail System. The TRIGEN™ Low Profile Bone Screw therefore has the following indications:

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).

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

META-TAN™ Nails are indicated for fractures of the femur including 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; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, 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; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

The TRIGEN™ Low Profile Bone Screw is intended for single use only.

Comparison to Technological Characteristics with the Predicate Device
Device comparisons described in this premarket notification demonstrated that the proposed TRIGEN™ Low Profile Bone Screws are substantially equivalent to the legally marketed primary predicate devices cleared in K111025 with regard to intended use, indications for use, and performance characteristics.

The subject TRIGEN™ Low Profile Bone Screws feature characteristics as previously cleared in K111025 with the primary differences being a design change in the tip of the screw. The subject devices feature identical indications for use and intended use as the TRIGEN™ Low Profile Bone Screws offered in K111025.

Summary of Pre-Clinical Testing

- Insertion Torque Evaluation – Testing evaluated the performance of the subject device compared to the original design. Test results showed the TRIGEN™ Low Profile Screws with the design change to the screw tip requires less insertion torque than the predicate. The modified TRIGEN™

Low Profile Bone Screw would therefore be expected to have a superior insertion torque performance as compared to the predicate design.

Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in the FDA Guidance , "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72.

Substantial Equivalence Information

The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the TRIGEN™ Low Profile Bone Screws cleared via premarket notification K111025**.**

Table 5.1 : Substantially Equivalent Predicates to the TRIGEN™ Low Profile Bone Screws

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	TRIGEN™ Low Profile Bone Screws	K111025	July 1, 2011

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the modified TRIGEN™ Low Profile Bone Screws. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate device.