April 11, 2019

Syntec Scientific Corporation
% Nicole Tseng
Regulatory Affairs Specialist
Syntec Scientific Corporation - Taipei Office
3F., No.96, Sec.3, Zhongxio East Road Da'An Dist.
Taipei, 10652 Taiwan R.O.C.

Re: K181296
Trade/Device Name: Syntec Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 8, 2019
Received: March 13, 2019

Dear Nicole Tseng:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.04.11 14:14:43 -04'00'

FOR 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181296

Device Name

SYNTEC FEMORAL NAIL SYSTEM

Indications for Use *(Describe)*

The Syntec Femoral Nail System is indicated for long bone fracture fixation which may include the following: Fractures, and tumor resections; Fractures proximal to a total knee arthroplasty; Supracondylar and ipsilateral fractures; Delayed union fractures; Open and closed femur shaft fractures; Combined inter and subrochanteric fractures; High subtrochanteric fractures; Pseudoarthrosis and correction osteotomy; Pathological fractures, impending pathologic and tumor resections; Pertrochanteric fractures; and Nonunions and malunions.

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.

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SYNTEC SCIENTIFIC

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This summary of 510(k) information is being submitted in accordance with the requirement of SMDA 1990 and 21CFR 807.92.

510(k) SUMMARY

Submitted By:	Syntec Scientific Corporation
Address:	No.2, Kung San Road Chuan Shing Industrial Zone, Shen Kang, Chang Hua Hsien, Taiwan R.O.C. TEL: +886-4-798-7099 FAX: +886-4-798-7077
Date Summary Prepared:	2018-05-11
Contact person:	Nicole Tseng
Name of the device:	Syntec Femoral Nail System
Trade or proprietary name:	Syntec Femoral Nail System
Common or usual name:	Intramedullary Nail
Classification name:	Intramedullary Fixation Rod
Produce code:	HSB
Regulation number:	21CFR888.3020
Class:	Class II
Predicate devices:	Trigen Trochanteric Antegrade Nail (K040462) Syntec Humeral Nail System (K161327) Syntec-Taichung Non-sterile Interlocking Nail System (K984543)
Prior Submission:	None

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1. Description of the Device

The Syntec Femoral Nail System are manufactured from commercially SUS316L (stainless steel) and Ti-6AL-4V (Titanium alloy). It is an intramedullary (IM) nail with a 5^{o} proximal bend allows the nail to be inserted through the tip of the greater trochanter for an easier surgical approach. These nails have a 135° recon screw angle for easier placement of two 6.3 mm Recon Screws into the femoral neck and ø5mm internal hex captured screws in various lengths for cross-screw fixation in both the proximal and distal portion of the nail. Also, an End Cap ø13 in 3, 5, 10, 15mm lengths is available for proximal closing of the nail. The Syntec Femoral Nail System (nail, screw and end cap) are provided Non-Sterile and single use only. Also, it is not for spinal use. Associated instrumentation such as aiming device for proximal and distal, insertion guide wire, drill accessories, system and removal instruments are available with the system.

2. Intended Use

The Syntec Femoral Nail System is indicated for long bone fracture fixation which may include the following: Fractures, and tumor resections; Fractures proximal to a total knee arthroplasty; Supracondylar and ipsilateral fractures; Delayed union fractures; Open and closed femur shaft fractures; Combined inter and subrochanteric fractures; High subtrochanteric fractures; Pseudoarthrosis and correction osteotomy; Pathological fractures, impending pathologic and tumor resections; Pertrochanteric fractures; and Nonunions and malunions.

3. Technological Characteristics, comparison to predicate device

Syntec Femoral Nail System is identical to the Trigen Trochanteric Antegrade Nail, Syntec-Taichung Non-sterile Interlocking Nail System, and Syntec Humeral Nail System cleared for market in 510(k) K040462, K984543 and K161327 and essentially Substantially Equivalent (SE) to the predicate. The indications for use for the Syntec Femoral Nail System are patterned after the predicate devices and supported by an extensive collection of literature references.

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Syntec Femoral Nail System and Trigen Trochanteric Antegrade Nail

	Subject device	Predicate Device
Device Name	Syntec Femoral Nail System	Trigen Trochanteric Antegrade Nail
Applicant	Syntec Scientific Corporation	SMITH & NEPHEW, INC.
510(k)	K181296	K040462
Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Titanium Alloy (Ti6AL-4V)
Nail Diameter	ø10 , ø11 , ø12 , ø13 , ø14	ø10 , ø11.5 , ø13
Nail Length	From 320 mm to 460 mm (in 20 mm increments)	From 300 mm to 500 mm (in 20 mm increments)
Nail Type	Left and Right	Left and Right
Screw Dia.	ø5.0 mm Internal Hex Captured	ø5.0 mm Internal Hex Captured
Screw Length	From 30 mm to 100 mm (in 5 mm increments)	From 25 mm to 110 mm (in 5 mm increments)
Recon Screw Dia.	ø6.3 mm Recon Screw	ø6.4mm Recon Screw
Actual size of Recon Screw Dia.	ø6.3mm	ø6.3mm
Recon Screw Length	From 65mm to 120 mm (in 5 mm increments)	From 65mm to 125 mm (in 5 mm increments)
Nail Caps Diameter	ø 13	ø 13
Nail Cap Length	in 3,5, 10,15 mm lengths	in 0,5, 10,15, 20 mm lengths

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Syntec Femoral Nail System and Syntec Humeral Nail System

	Subject device	Predicate Device
Device Name	Syntec Femoral Nail System	Syntec Humeral Nail System
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K181296	K161327
Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)
Nail Caps Diameter	ø 13	ø 8 and ø 9
Nail Cap Length	in 3,5, 10,15 mm lengths	in 9 mm lengths

Syntec Femoral Nail System and Syntec-Taichung Non-sterile Interlocking Nail System

	Subject device	Predicate Device
Device Name	Syntec Femoral Nail System	Syntec-Taichung Non-sterile Interlocking Nail System
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K181296	K984543
Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)
Screw Dia.	ø5.0 mm Internal Hex Captured	ø5.0 mm Internal Hex Captured
Screw Length	From 30 mm to 100 mm (in 5 mm increments)	From 20 mm to 90 mm (in 5 mm increments)
Recon Screw Dia.	ø6.3 mm Recon Screw	ø6.4mm Screw
Recon Screw Length	From 65mm to 120 mm (in 5 mm increments)	From 30mm to 90 mm (in 5 mm increments) full thread

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4. Performance Data

The procedure of evaluating the device tests was according to the standard of ASTM-F1264-16. The testing was done to our Syntec Femoral Nail System device to demonstrate substantial equivalence.

5. Substantial Equivalence

We believe that Syntec Femoral Nail System does not add new or increased risks and complications, based on current engineering technology and clinical results published about intramedullary rods as well as based on what has been previously cleared by FDA.

According device test report of performance data demonstrate that the Syntec Femoral Nail is as safe and effective as K040462, K984543 and K161327. In addition, the Syntec Femoral Nail System has the same intended uses and indications, technological characteristics, and principles of operation to the predicate device. Thus, the Syntec Femoral Nail System is substantially equivalent in design, configuration, function, and indications for use to the Predicate Device.