September 3, 2019

Syntec Scientific Corporation
% Kavin Chu
Senior Regulatory Affairs Manager
Syntec Scientific Corporation - Taipei Office
3F., No.96, Sec. 3, Zhongxio East Road Da'An Dist.,
TAIPEI 10652
TAIWAN R.O.C

Re: K191617
Trade/Device Name: Syntec Tibial Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 31, 2019
Received: June 18, 2019

Dear Kavin Chu:

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,

for

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191617

Device Name

Syntec Tibial Nail System

Indications for Use *(Describe)*

The Syntec Tibial Nail System is intended to stabilize fractures of the proximal and distaltibia and the tibial shaft; certain pre-and post-isthmic fractures; open and closed tibial shaft fractures; and tibial malunions and non-unions

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 CORPORATION

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 of Summary Prepared:	2019-05-31
Contact person:	Kavin Chu
Name of the device:	Syntec Tibial Nail System
Trade or proprietary name:	Syntec Tibial Nail System
Common or usual name:	Intramedullary Nail
Classification name:	Intramedullary Fixation Rod
Produce code:	HSB
Regulation number:	21CFR888.3020
Class:	Class II
Primary Predicate:	Syntec-Taichung Non-Sterile Interlocking Nail System (K984543)
Additional Predicates:	Syntec Femoral Nail System (K181296) Synthes (USA) Tibial Nail System Ex (K040762)

1. Description of the Device

The Syntec Tibial Nail System are manufactured from commercially SUS316L (stainless steel) and Ti-6AL-4V (Titanium alloy). It is an intramedullary (IM) nail with a 12^{o} in the upper third of the reamed Tibial Nail. These nails will use 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 ø8.4 in 15mm lengths is available for proximal closing of the nail. The Syntec Tibial 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. Indications for Use

The Syntec Tibial Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; certain pre- and post-isthmic fractures; open and closed tibial shaft fractures; and tibial malunions and non-unions.

3. Technological Characteristics, Comparison to Predicate Device

Syntec Tibial Nail System is similar to our previous Syntec-Taichung Non-sterile Interlocking Nail System and Syntec Femoral Nail System; both of systems are cleared for market in 510(k) K984543, K181296 and essentially Substantially Equivalent (SE) to the predicate. The indications for use for the Syntec Tibial Nail System are patterned after the predicate devices and supported by an extensive collection of literature references.

The differences between subject and predicates system as below chart.

Syntec Tibial Nail System and Syntec-Taichung Non-sterile Interlocking Nail System K984543 (Tibial Nail)

	Subject device	Predicate Device
Device Name	Syntec Tibial Nail System	Syntec-Taichung Non-sterile Interlocking Nail System
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K191617	K984543

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Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L)
Nail Diameter	ø9, ø10, ø11, ø12, ø13	ø8, ø9, ø10, ø11, ø12, ø13, ø14
Nail Length	From 270 mm to 345 mm (in 15 mm increments)	From 270 mm to 420 mm (in 15 and 20 mm increments)
Proximal Shaft Angle	12^{o}	15^{o}

Syntec Tibial Nail System and Syntec Femoral Nail System K181296

(Internal Hex Captured Screw, End Cap)

	Subject device	Predicate Device
Device Name	Syntec Tibial Nail System	Syntec Femoral Nail System
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)		K181296
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 30 mm to 100 mm (in 5 mm increments)
End Caps Diameter	ø 8.4	ø 13
Nail Cap Length	in 15 mm lengths	in 3,5, 10,15 mm lengths

4. Technological Characteristics:

The Syntec Tibial Nail System is fabricated from stainless steel (SUS316L) per ASTM F138 and ASTM F139, titanium alloy (Ti6AL-4V) per ASTM F136. The design feature for the Syntec Tibial Nail System are similar to the predicate devices including dimensions, shape and sizes.

5. Summary of Performance Data (Nonclinical and/or Clinical)

***Clinical Test**

Clinical studies are not required to support substantially equivalent.

***Non-Clinical Test**

Biomechanical Test: The biomechanical tests ASTM F1264-16e1were performed to determine substantial equivalence for the Syntec Tibial Nail System including the performance of Tibial Nail and Internal Hex Captured Screw. Results indicate that the subject Tibial Nail and Internal Hex Captured Screw are substantially equivalent to legally marketed devices.

6. Substantial Equivalence

The Syntec Tibial Nail System has the same intended uses and indications, technological characteristics, and principles of operation to the predicate device. Thus, the Syntec Tibial Nail System is substantially equivalent in design, configuration, function, and indications for use to the Predicate Device.