Syntec Scientific Corporation
Nicole Tseng
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Syntec Scientific Corporation - Taipei Office
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Taipei, R.O.C. 10652
Taiwan

November 23, 2020

Re: K202935
Trade/Device Name: Syntec Femoral Nail Extended System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB

Dear Nicole Tseng:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 28, 2020. Specifically, FDA is updating this SE Letter due to an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Owens, OHT6: Office of Orthopedic Devices, 301-796-5650, Michaelc.Owens@fda.hhs.gov.

Sincerely,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2020.11.23 11:58:17 -05'00'

For Michael Owens
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

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October 28, 2020

Re: K202935
Trade/Device Name: Syntec Femoral Nail Extended System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 26, 2020
Received: September 29, 2020

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/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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2020.10.28 16:58:39 -04'00'

For Michael Owens
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)*

K202935

Device Name

Syntec Femoral Nail Extended 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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E-mail: fda@eagleseye.com.tw Regulatory Affairs Specialist

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

Special 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:	2020-09-26
Contact Person:	Nicole Tseng
Name of the Device:	Syntec Femoral Nail Extended System
Trade or Proprietary Name:	Syntec Femoral Nail Extended System
Common or Usual Name:	Intramedullary Nail
Classification name:	Intramedullary Fixation Rod and Accessories
Product Code:	HSB
Regulation Number:	21 CFR §8888.3020
Device Classification:	Class II
Classification Panel:	87- Division of Orthopedic Devices
Primary Predicate:	K181296 - Syntec Femoral Nail System
Additional Predicates:	K984543 - Syntec-Taichung Non-Sterile Interlocking Nail System (FEMUR:274-000/870)
Modification of a Legally Marketed Device:	K181296 - Syntec Femoral Nail System
Prior Submission:	None

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1. Description of the Device

The Syntec Femoral Nail Extended System are manufactured from commercially SUS316L (stainless steel) and Ti-6AL-4V (Titanium alloy). It is an intramedullary (IM) nail with a 5° 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 Extended 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 Extended 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 Previous Device

Syntec Femoral Nail Extended System is identical to the Syntec Femoral Nail System and Syntec-Taichung Non-Sterile Interlocking Nail System (FEMUR:274-000/870) cleared for market in 510(k) K181296, K984543 and essentially Substantially Equivalent (SE) to the predicate. The indications for use for the Syntec Femoral Nail Extended System are patterned after the predicate devices and supported by an extensive collection of literature references for a long time.

The modified nails are fabricated from stainless steel (SUS316L) per ISO 5832-1:2007/ASTM F138-13 and Titanium-6 Aluminum-4 Vanadium Eli (Extra Low Interstitial) Alloy per ISO

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5832-3:1996/ASTM F136-13 as same as previous devices. The design feature for the nail is same to the predicate devices including shape, style and type. Also, the final finished form is identical to Syntec (K181296) in formulation, processing, and sterilization and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Even though the global geometry in dimensions is 1 mm less in revised K181296 nail type for better anatomical fit , the material and manufacturing process is identical in formulation, processing and sterilization. Also, the modified nail's diameter and length are between K984543's femur nail type.

Syntec Femoral Nail Extended System and Two type of Syntec Femoral Nail System

	Subject device	Predicate Device	Add. Predicate Device
Device Name	Syntec Femoral Nail Extended System	Syntec Femoral Nail Extended System	Syntec-Taichung Non-Sterile Interlocking Nail System (FEMUR:274-000/870)
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K202935	K181296	K984543
Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L)
Nail Diameter	ø9	ø10 , ø11 , ø12 , ø13 , ø14	ø 8 , ø9, ø10 , ø11 , ø12 , ø13 , ø14, ø15 , ø16
Nail Length	From 260 mm to 400 mm (in 20 mm increments)	From 320 mm to 460 mm (in 20 mm increments)	From 240 mm to 480 mm (in 20 mm increments)
Nail Type	Left and Right	Left and Right	Standard

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

***Clinical Test**

Clinical data and conclusions were not needed for these devices.

***Non-Clinical Test**

The Syntec Femoral Nail Extended System was considered for conformance to dimensional and material mechanical property standards ASTM F138-13 and F136-13. Those nails in the scope of this submission were in conformance with those standards and are therefore substantially equivalent to the predicate devices.

In addition, mechanical strength comparison, analysis of results, engineering justifications, dimensional and material comparisons were conducted to determine substantial equivalence to the predicates.

5. Substantial Equivalence

The Syntec Femoral Nail System has the same intended uses and indications, technological characteristics, and principles of operation to the predicate device. Stress analysis result, risk analysis and design control activities including verification activities were conducted to demonstrate the subject device does not raise any different questions of safety or effectiveness associated with smaller diameter devices. Thus, the Syntec Femoral Nail System is substantially equivalent in design, configuration, function, and indications for use to the Predicate Device.