DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 8, 2017

Syntec Scientific Corporation
Kavin Chu
Regulatory Affairs Manager
Syntec Scientific Corporation - Taipei Office
3F., No. 96, Sec. 3, Zhongxio East Road Da'an Dist.,
Taipei, 10652 TW

Re: K161327
Trade/Device Name: Syntec Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 21, 2017
Received: May 10, 2017

Dear Mr. 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. 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)*
K161327

Device Name
SYNTEC HUMERAL NAIL SYSTEM

Indications for Use *(Describe)*
THE SYNTEC HUMERAL NAIL SYSTEM IS INDICATED FOR FRACTURES OF THE PROXIMAL HUMERUS, INCLUDING 2-PART SURGICAL NECK FRACTURES, 3-PART FRACTURES, AND 4-PART FRACTURES, PROXIMAL HUMERAL FRACTURES WITH DIAPHYSEAL EXTENSION INTO THE SHAFT, AND IMPENDING PATHOLOGIC HUMERAL FRACTURES.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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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:	April 29, 2016
Contact person:	Kavin Chu
Name of the device:	Syntec Humeral Nail System
Trade or proprietary name:	Syntec Humeral Nail System
Common or usual name:	Intramedullary Rod
Classification name:	Intramedullary Fixation Rod
Produce code:	HSB
Regulation number:	888.3020
Class:	Class II
Predicate devices:	I.T.S. IM Nail Systems CFN-CTN-CHN (K132945)
Prior Submission:	None

1. Description of the Device

The Syntec Humeral Nail System are manufactured from commercially SUS316L (stainless steel) and Ti-6AL-4V (Titanium alloy). It is an intramedullary (IM) straight nail with a 5^{o} proximal bend configuration to fit the anatomy of the humerus and is inserted proximally over ø2.0 calibrated guide wires. Those nail accepts only an ø3.8mm Cortical Screw in various lengths for cross-screw fixation in both the proximal and distal portion of the nail. Also, an End Cap ø8 ~ ø 9 in 9mm lengths is available for proximal closing of the nail. The Syntec Humeral Nail System

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(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 Humeral Nail System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension into the shaft, and impending pathologic humeral fractures.

3. Technological Characteristics, comparison to predicate device

Syntec Humeral Nail System is identical to the I.T.S. IM Nail Systems CFN-CTN-CHN cleared for market in 510(k) K132945 and essentially Substantially Equivalent (SE) to the predicate.

The indications for use for the Syntec Humeral Nail System are patterned after the predicate devices and supported by an extensive collection of literature references.

	Subject device	Predicate Device
Device Name	Syntec Humeral Nail System	I.T.S. IM Nail Systems CFN-CTN-CHN
Applicant	Syntec Scientific Corporation	I.T.S. GmbH
510(k)	K161327	K132945
Material Comparison	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Titanium Alloy (Ti6AL-4V)
Nail Diameter	ø 7 , ø 8 , ø 9	ø 7 , ø 8 , ø 9
Nail Length	From 160mm to 240mm (in 20mm increments)	From 140mm to 320mm (in 10 and 20mm increments)
Nail Type	Standard	Left and Right

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Screw Length	From 20mm to 70mm (in 5mm increments)	From 20mm to 70mm (in 2mm and 5mm increments)
Screw Diameter	ø3.8mm Cortical Screw	ø3.5mm Cortical Screw
End Cap Diameter	ø 8 , ø 9	No information provide
End Cap Length	9mm	in +0,+5, +10,+15, +20, +25 & +30 lengths

4. Performance Data

The procedure of evaluating the device tests was according to the standard of ASTM-F1264-14. The testing was done to our Syntec Humeral Nail System device to demonstrate substantial equivalence.

5. Substantial Equivalence

We believe that Syntec Humeral 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 Humeral Nail is as safe and effective as K132945. In addition, the Syntec Humeral Nail System has the same intended uses and indications, technological characteristics, and principles of operation to the predicate device. Thus, the Syntec Humeral Nail System is substantially equivalent in design, configuration, function, and indications for use to the I.T.S. IM Nail Systems CFN-CTN-CHN (K132945).