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

May 5, 2020

Re: K200933
Trade/Device Name: Syntec Non-Sterile Steinmann Pins System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW, HTY
Dated: April 7, 2020
Received: April 7, 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,

for
Brent L. Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal 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)*
K200933

Device Name
Syntec Non-Sterile Steinmann Pins System

Indications for Use *(Describe)*
The Steinmann pins are provided non-sterile. The devices are indicated for use in fracture fixation, for healing of facile bone fragments, for osteotomies in the presence of adequate immobilization, as guide pins for insertion of other implants.

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.

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

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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.

Special 510(k) Summary

Submitted By:	Syntec Scientific Corporation
Address:	Syntec Scientific Corporation - Taipei Office 3F., No.96, Sec. 3, Zhongxio East Road Da'An Dist., Taipei, Taiwan 10652 R.O.C. TEL: +886-4-798-7099 FAX: +886-4-798-7077
Date of Summary Prepared:	2020-03-31
Contact person:	Nicole Tseng
Name of the device:	Senior Regulatory Affairs Specialist
Trade or proprietary name:	Syntec Non-Sterile Steinmann Pins System
Common or usual name:	Smooth Or Threaded Metallic Bone Fixation Fastener
Product code:	JDW, HTY
Regulation number:	21CFR888.3040
Class:	Class II
Modified devices:	Non-Sterile Kirschner Wires and Steinmann Pins (K983121)
Prior Submission:	None

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1. Description of the Device

The Syntec Non-Sterile Steinmann Pins System is modify from our own device from K983121-Non-Sterile Kirschner Wires and Steinmann Pins product systm.

2. Intended Use

The Steinmann pins are provided non-sterile. The devices are indicated for use in fracture fixation, for healing of facile bone fragments, for osteotomies in the presence of adequate immobilization, as guide pins for insertion of other implants.

3. Technological Characteristics Comparison to Previous Device

The Syntec Non-Sterile Steinmann Pins System is identical to our previous cleared for market in 510(k) K983121-Non-Sterile Kirschner Wires and Steinmann Pins product system and essentially Substantially Equivalent (SE) to the predicate. The indications for use for this system are patterned after the predicate devices and supported by an extensive collection of literature references.

4. Technological Characteristics:

The modify Pins are fabricated from stainless steel (SUS316L) per ASTM F138-13.The design feature for the Non-Sterile Steinmann Pins System is similar to the predicate devices including dimensions, shape, style and sizes.

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

***Clinical Test**

Clinical data and conclusions were not needed for these devices.

***Non-Clinical Test**

Performance test are not required to support substantially equivalent in special 510k.

The Syntec Non-Sterile Steinmann Pins System was considered for conformance to dimensional and material mechanical property standards ASTM F138-13, ASTM F366 -10 and ISO 5838-1. All items in the scope were in conformance with those standards and are therefore substantially equivalent to the predicate devices.

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In addition, Syntec Non-Sterile Steinmann Pins System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

***Conclusions**

The analysis information presented in this submission demonstrates that the subject device is substantially equivalent to the predicate devices.

6. Substantial Equivalence

We believe that Syntec Non-Sterile Steinmann Pins System does not add new or increased risks and complications, based on current engineering technology and clinical results published about pins as well as based on what has been previously cleared by FDA.

In conclusion, the Syntec Non-Sterile Steinmann Pins System has the same intended uses and indications, technological characteristics, and principles of operation to the predicate device. Thus, the Syntec Non-Sterile Steinmann Pins System is substantially equivalent in design, configuration, function, and indications for use to the previous own device.