K092889 #1/3

JUN 25 2010

510(K) SUMMARY

Submitter's name :	**Syntec Scientific Corporation**
Address :	**2, Kung San Rd,** **Chuan Shing Industrial Zone,** **Shen Kang,** **Chang Hua,** **Taiwan** **Tel : 886-4-7987099** **Fax: 886-4-7987077**
Contact person :	Carol Chang
Name of the device :	**Syntec Osteo-plate and screw Fixation**
Trade or proprietary name :	**Syntec Osteo-plate and screw Fixation**
Common name:	**bone plate and bone screw**
Classification name :	**Smooth or threaded metallic bone fixation fastener.**
Produce Code :	**HWC, HRS**
Regulation Number :	**888.3030, 888.3040**
Class :	**II**
Predicate device:	**Syntec-Taichung Non-sterile Bone Plate and Screw Implants (K983495)**
Preparation of the date:	**August 01, 2009**

Material:

The Syntec Osteo-plate and screw Fixation provides two materials, Stainless Steel and Titanium Alloy (Ti-6Al-4V) and commercially followed by ASTM F138, and ASTM F136.

Description of the Device:

Those are designed with various sizes of partially and fully threaded to satisfy with different kinds of fractures as using on small bones or large bones. The subject components are plates available in width from 3.8mm to 17.5mm, in total length from 15mm to 319mm and the hole numbers are 2 to 22 holes. The threads of the screws are available in diameters from 2.4mm to 7.3mm, and in length from 6mm to 180mm. Those

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screws have been designed for fitting on different symptoms of fractures and the plates have been designed to distribute for local anatomies and should be necessary to be used with its intended screws. Basically, the screws used to fasten plates onto bone, or, as lag screws, to hold together fragments of bone. We have totally the same kinds of the screws and plates as the predicate devices' functions, but with self-tapping or self-drilling to promote the operation efficiency. Besides this, we have another alternative screws and plates which are designed with locking head of the screws taken place with the traditional screw head, and threaded aside locking hole of the plates taken place with the aside plain hole of the plates.

Indications for Use:

Syntec Osteo-plate and screw Fixation is intended to be used on small bones or large bones for fracture fixation, including the fractures of clavicle, scapula, pelvis, long bones (humerus, ulna, radius, femur, tibia, and fibula), and small bones (metacarpals, metatarsals, and phalanges).

Technology Characteristics:

The design, materials and indications for use of the Osteo-plate and screw are equivalent to device previously approved for market in the United States.

Device Comparison Table:

	Predicate Device	Applicant
Sponsor	Syntec Scientific Corporation	Syntec Scientific Corporation
Device name	Syntec-Taichung Non-sterile Bone Plate and Screw implants	Syntec Osteo-plate and screw Fixation
510(k) number	K983495	-
Regulation number/ name/ class/ product code	Class II §888.3030, 888.3040 Single/ Multiple component metallic bone fixation appliances and accessories/ Smooth or threaded metallic bone fixation fastener HRS, HWC	Class II §888.3030, 888.3040 Smooth or threaded metallic bone fixation fastener HRS, HWC
Intended Use	The bone plates and screws are provided non-sterile. The	Syntec Osteo-plate and screw Fixation is intended to be used on

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	devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia, and fibula), and small bone (metacarpals, metatarsals, and phalanges).	mini, small bones or large bones for fracture fixation, including the fractures of clavicle, scaula, pelvis, long bone (humerus, ulna, radius, femur, tibia, and fibula), and small bone (metacarpals, metatarsals, and phalanges).
Diameters of screws	From 1.5mm to 7.3mm	From 2.4mm to 7.3mm
Lengths of plates	From 17mm to 262mm	From 15mm to 319mm
Materials	Stainless steel and titanium alloy (Ti-6Al-4V)	Stainless steel and titanium alloy (Ti-6Al-4V)

Performance Data:
The test results of the Compression strength of plates and screws, Pull-out strength of screws, and Torsional strength of screws were compared to the results of the Syntec-Taichung Non-sterile Bone Plate and Screw implants and demonstrated substantial equivalence.

Conclusion:
The Syntec Osteo-plate and screw Fixation is no new issue of safety or effectiveness. The device does not additional concerns regarding safety and effectiveness and may, therefore, be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 25 2010

Syntec Scientific Corporation
% Ms. Carol Chang
3F1. 96 Chung Hsiao E. Rd. Sec. 3
Taipei
China (Taiwan) 106

Re: K092889
Trade/Device Name: Syntec Osteo-plate and screw Fixation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 10, 2010
Received: June 15, 2010

Dear Ms. Chang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Indications for Use

510(k) Number (if known): K092889
Device Name: Syntec Osteo-plate and screw Fixation
Indications for Use:

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Prescription Use _____X_____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092889