K090839

510(K) SUMMARY

APR 24 2009

Submitter's name	**Syntec Scientific Corporation**
Address	**2, Kung San Rd,** **Chuan Shing Industrial Zone,** **Shen Kang,** **Chang Hua, Taiwan.** **Telephone :886-4-7987099** **Fax: 886-4-7987077**
Contact person	**Carol Chang**
Name of the device	**Syntec-Taichung Bone Plates and Screw**
Implant	
Trade or proprietary name	**Syntec-Taichung Bone Plates and Screw**
Implant	
Classification name	**Plate, Fixation, Bone**
Prode Code	**HRS**
Regulation Number	**888.3030**
Class	**II**
Predicate device:	**Syntec-Taichung Bone Plates and Screw**
Implant	

Description of the Device:

The plate is manufactured from commercially 316LS Stainless Steel which in conformance with ASTM F138 and an alternative material which is Pure Titanium. The plates designed are from 1.5mm to 6.5mm thickness, from 6.5mm to 17.5mm width, and are available variously in length from 24.0mm (2 holes) to 394.0mm (22 holes). It should assembly with the same screw that was the predicate device in concurrence by FDA, (K983495).

Indications for Use:

The bone plates and screws are provided non-sterile. The 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).

Substantially Equivalence:

The predicate device information provided supports the substantially equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 24 2009

Re: K090839
Trade/Device Name: Syntec-Taichung Bone Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: March 27, 2009
Received: March 27, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson DDS PhD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090839

Device Name: Syntec-Taichung Non-Sterile Bone Plate and Screw Implant

Indications for Use:

The bone plates and screws are provided non-sterile. The 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).

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 General, Restorative, and Neurological Devices

510(k) Number K090839