

510(k) Summary of Safety and effectiveness

- **Sponsor :** Syntec-Taichung Medical Instruments Co., Ltd.
2, Kung San Road, Chuan Shing Industrial Zone, Shen Kang,
Chang Hua, Taiwan. 509
Phone / FAX: 886-4-7987099 / 886-4-7987077
Contact Person: Ted Y. Shi
- **Proprietary Name :** Syntec-Taichung Non-sterile Bone Plate and Screw Implants
- **Common Name :** Bone fixation plate and screw
- **Classification Name :** Class II, CFR 888.3030 and 888.3040
- **Device Product Code :** 87 HRS and 87 HWC
- **Material :**
The non-sterile bone plates and screws are manufactured from commercially 316 LS stainless steel and titanium alloy (Ti-6Al-4V).
- **Indication 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).
- **Description of the Device :**
This system makes up of non-sterile bone plate and screw implants. The plates are devices, which are fastened to bone for purpose of providing fixation. They are principally differentiated by their function. Thus there are four kind of styles: Dynamic Compression Plate (DCP), tubular, special, and mini. The shape of the plate is an adaptation of the plate to the local anatomy and doesn't denote any function. Thus the name depends on the biomechanical function the plate is performing. Every plate is divided various types as following:

Plate Name	Geometry Shape
DCP	narrow, narrow lengthening, broad, and broad lengthening straight
Tubular	semi-tubular, one-third, and quarter
Special	L-shaped, T-shaped, spoon, cobra, lateral tibial head, condylar

Mini

buttress, head, and hook

Straight, L-shaped, T-shaped, condylar, special, and reconstruction

The plates are manufactured from commercially 316 LS stainless steel; however, all of titanium plates except mini are included above-style. They range in thickness from 1.0 to 5.0 mm, width from 3.8 to 17 mm, length from 17 to 262 mm, and hole number from 2 to 20 holes.

On the other hand, the screws used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. Thus there are four kind of style: cortex, cancellous, malleolar, and cannulated. All screws have a hexagonal recess; this feature has proven itself to be of great advantage at the time of the screw removal and insertion.

The screws are manufactured from commercially 316 LS stainless steel. However, all of titanium screws except malleolar were included above-style. They range in thread diameter from 1.5 to 7.3 mm, total length from 6 to 150 mm, and hexagonal socket width from 1.5, 2.5, or 3.5 mm.

➤ **Basis of Substantial Equivalence :**

A comparison of the non-sterile bone plate and screw implants described in this submission and Synthes bone plate/screw shows that they are very similar or identical in terms of design, sizes, material and appliance. Based on this information, Syntec-Taichung believes that the non-sterile bone plate and screw implants are substantially equivalent to Synthes bone plate and bone screw.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1998

Mr. Ted Y. Shi
Vice-Chairman
Syntec-Taichung Medical Instruments Company, Limited
2, Kung San Road, Chuan Shing Industrial Zone,
Shen Kang, Chang Hua, Taiwan 509

Re: K983495
Syntec-Taichung Non-sterile Bone Plate and Screw Implants
Regulatory Class: II
Product Codes: HWC and HRS
Dated: November 25, 1998
Received: December 1, 1998

Dear Mr. Shi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

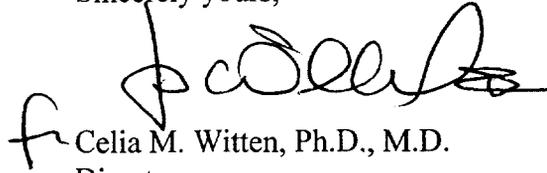
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the

Page 3 – Mr. Ted Y. Shi

Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

Celia M. Witten, Ph.D., M.D.

Director

Division of General and Restorative Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K983495

Device Name: Syntec-Taichung Non-sterile Bone Plate and Screw Implants

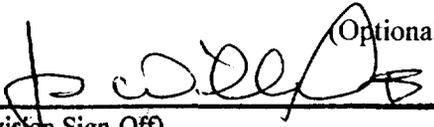
Indications for use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983495