

3/5/99

K98 4602

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 Unreamed Interlocking Nail System
- **Common Name :** Various Types of Unreamed Intramedullary Fixation Implants
- **Classification Status :** Class II, CFR 888.3020
- **Device Product Code :** 87 HSB
- **Material:** This device is manufactured from commercially 316LS stainless steel and titanium alloy (Ti-6Al-4V).
- **Indication for Use :**
The Unreamed Interlocking Nail System is provided non-sterile. The implants are inserted into the medullary(bone marrow) canal of long bones(femur, and tibia) for the fixation of fractures.
- **Description of the Device :**
The interlocking system makes up of Femoral, Tibial Nail and bolt screws. The bolt screws are utilized with the different interlocking nail. The interlocking nails have the same features such as:
 - **Dynamic locking:** Using the proximal oval hole permits axial loading with rotational stability.
 - **Anatomical design:**
 - ◇ **Femur:** The 1.6m radius of the Unreamed Femoral Nail corresponds closely with the average anatomical curvature of the femur.
 - ◇ **Tibia:** The curvature of 8° in the upper third of the Unreamed Tibial Nail allows for easy insertion and good anatomical fit.
 - **Distal locking:** Through two medial holes, additional locking is also possible in the

anatomical seat.

- Easy insertion: The curvature of the posterior aspect of the nail reduces damage to the interior posterior cortical surface during insertion.

The dimension of the unreamed interlocking nail ranges in diameter from 8 to 12 mm and total length 255 to 480 mm.

The locking bolt screws have high strength, self-tapping and easy locking technique.

The dimension of the bolt screw ranges in thread diameter from 3.9, 4.9, and 5.0mm and total length 20 to 125 mm.

- **Basis of Substantial Equivalence :**

A comparison of the non-sterile Unreamed Interlocking Nail System described in this submission and Synthes–Titanium Unreamed Femoral Nail has been commercial device that they are very similar or identical in terms of design, sizes, material and appliance. Based on this information, Syntec-Taichung (Taiwan) believes that the non-sterile Unreamed Interlocking Nail System is substantially equivalent to Synthes–Titanium Unreamed Femoral Nail.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

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

Re: K984602
Syntec-Taichung (Taiwan) Non-sterile
Unreamed Interlocking Nail System
Regulatory Class: II
Product Code: HSB
Dated: December 22, 1998
Received: December 28, 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.

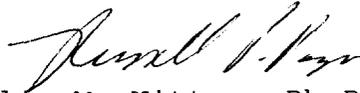
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Ted Y. Shi

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, 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 Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for 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): K984602

Device Name: Syntec-Taichung Non-sterile Unreamed Interlocking Nail System

Indications for use:

The Unreamed Interlocking Nail System is provided non-sterile. The implants are inserted into the medullary(bone marrow) canal of long bones(femur, and tibia) for the fixation of fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

Ann Payne for CDRH
Division **Sign-Off**
Division of **General Restorative Devices**
510(k) Number K984602