3/2/99

K984364

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 Small Orthopedic Fixation System
- **Common Name :** Small External Fixation System
- **Classification Status :** Class II, CFR 888.3030
- **Device Product Code :** 87 KTT
- **Material:** This device is manufactured from commercially stainless steel.
- **Indication for Use :**

  The Small Orthopedic Fixation System is provided non-sterile. The implants by the External Fixation Instrument may be used for highly comminuted closed fracture of hand, wrist, foot and tarsus ; for severe open fractures; for complex soft-tissue damages; or for dislocated joint fractures.
- **Description of the Device :**

  The Small Orthopedic Fixation System makes up of instrument and implants. The instrument is utilized with the implants. The implants are divided two kinds of styles: Schanz Screw, and Kirschner Wire. The dimension of the Schanz Screw ranges in thread diameter from 1.6 to 3.0 mm, thread length 15 mm, and total length 150, 200 mm; The dimension of Kirschner Wire with Threaded Tip ranges in thread diameter from 3.0/4.0 mm, total length from 80 mm.
- **Basis of Substantial Equivalence :**

  A comparison of the non-sterile Small Orthopedic Fixation System described in this submission and Electro-Biology -- EBI Small External Fixator (S/E/F/) 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 Small Orthopedic Fixation System is substantially equivalent to Electro-Biology -- EBI Small External Fixator (S/E/F/).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 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: K984364
Syntec-Taichung (Taiwan) Non-sterile
Small Orthopedic Fixation System
Regulatory Class: II
Product Code: KTT
Dated: December 2, 1998
Received: December 7, 1998

Dear Mr. Shi:

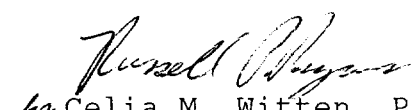
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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. 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): _____

Device Name: Syntec-Taichung Non-sterile Small Orthopedic Fixation System

Indications for use:

The Small Orthopedic Fixation System is provided non-sterile. The implants by the External Fixation Instrument may be used for highly comminuted closed fracture of hand, wrist, foot and tarsus ; for severe open fractures; for complex soft-tissue damages; or for dislocated joint 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 OR Over-The-Counter-Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nam Nguyen for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 115 K584364