

K983121

**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 :** Non-sterile Kirschner Wires and Steinmann Pins
- **Common Name :** Bone fixation fasteners
- **Classification Name :** Class II, CFR 888.3040
- **Device Product Code :** 87 HTY and 87 JDW
- **Material:** This device is manufactured from commercially 316 LS stainless steel.
- **Indication for Use :**  

The Kirschner Wires and Steinmann Pins are provided non-sterile. The devices are indicated for use in fracture fixation, for healing of facile bone fragments, for osteotomies in the presence of adequate immobilization, as guide pins for insertion of other implants.
- **Description of the Device :**  

This system makes up of non-sterile, shank and threaded Kirschner Wires and Steinmann Pins. The Kirschner Wires ranges in length from 101.6 to 300 mm and ranges in diameter from 0.7 to 1.6 mm. The Steinmann Pins ranges in length from 70 to 400 mm and ranges in diameter from 0.8 to 4.8 mm. They are available with four-point style: diamond, trocar, both ends diamond and both ends trocar. The 9”(230 mm) shank and threaded Kirschner Wires and Steinmann Pins are usually available with fracture fixation fasteners.

## Appendix A

### Sterilization Information-Non-sterile Device

These devices are provided non-sterile. The recommended sterilization parameters for non-sterile devices are as follows:

Method	Cycle	Time	Temperature
Steam	Vacuum	6 min	132~135 °C



OCT 5 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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: K983121  
Non-sterile Kirschner Wires and Steinmann Pins  
Regulatory Class: II  
Product Codes: HTY and JDI  
Dated: September 1, 1998  
Received: September 8, 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.

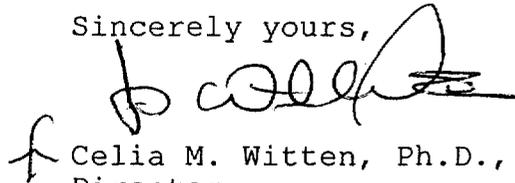
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



f 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

Page 1 of 1

510(K) Number (if known): K983121

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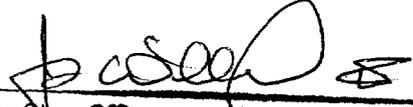
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Concurrence of CDRH, Office of Device Evaluation (ODE) .....

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of **General Restorative Devices**  
510(k) Number K983121