

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 DHS/DCS Plate System
- **Common Name :** Proximal Femoral Implant
- **Classification Status :** Class II, CFR 888.3030
- **Device Product Code :** 87 JDO
- **Material:**
This device is manufactured from commercially 316 LS stainless steel and titanium alloy (Ti-6Al-4V).

- **Indication for Use :**
The DHS/DCS Plate System is provided non-sterile. The device may be used for fixation of fractures of the proximal femur, such as femoral neck, trochanteric, pertrochanteric, or intertrochanteric zones.

- **Description of the Device :**
The system makes up of DHS/DCS Plates, DHS/DCS Screw, DHS/DCS Compression Screw, and 4.5 mm Cortex Screw (self-tapping). The DHS Plates are available with barrel length 25 mm and 38 mm, and barrel angles 135° , 140° , 145° , and 150° . The standard barrel length is 38 mm. Otherwise, the self-tapping 4.5 mm Cortex Screw may be used to fix the DHS/DCS Plates to the femoral shaft.

The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 26 mm and outer diameter 4.0 mm.

The thread of DHS/DCS Screw has a buttress type. The DHS/DCS Screw is available with thread length 22 mm, total length from 50 to 145 mm, outer diameter 12.5 mm, and shaft diameter 8.0 mm.



DEC 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ted Y. Shi
President
Syntec-Taichung (Taiwan)
2, Kung San Road
Chuan Shing Industrial Zone
Shen Kang, Chan Hua Taiwan 509

Re: K983873
Trade Name: Non-sterile DHS/DCS Plate System
Regulatory Class: II
Product Codes: KTT and HWC
Dated: October 27, 1998
Received: November 2, 1998

Dear Mr. Shi:

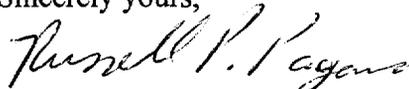
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Page 1 of 1

510(K) Number (if known): K983873

Device Name: Syntec-Taichung Non-sterile DHS/DCS Plate System

Indications for use:

The DHS/DCS Plate System is provided non-sterile. The device may be used for fixation of fractures of the proximal femur, such as femoral neck, trochanteric, pertrochanteric, or intertrochanteric zones.

(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)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K983873