



K983787

### Summary of Safety and Effectiveness Information

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
  
(610) 647-9700

**CONTACT:** Angela Silvestri

**DEVICE NAME:** Synthes Proximal Tibia Plating System

**DEVICE CLASSIFICATION:** 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

**PREDICATE DEVICE:** Zimmer Periarticular Plating System  
Synthes Narrow DCP  
Howmedica Alta Plating System

**DESCRIPTION OF DEVICE:** The Proximal Tibia Plating System consists of 3.5 mm and 4.5 mm Plates and a 3.5/4.5 mm Washer. The plates are anatomically contoured; feature a low profile, limited contact design, and are available in right and left versions. The heads of the plates include holes for K-wires or sutures, if necessary. The 3.5 mm Plates are used with 3.5 mm cortex, 4.0 mm cancellous, and 4.5 mm cannulated screws. The 4.5 mm Plates are used with 4.5 mm cortex, 6.5 mm cancellous, 7.0 mm and 7.3 mm cannulated screws. When used with the 3.5/4.5 washer, the 4.5 mm Plates can also be used with all of the screws that fit the 3.5 plates; the washer prevents the screw head from pulling through the plate holes. This device system is manufactured from stainless steel.

This device system is manufactured from stainless steel.

**INDICATIONS:** The Proximal Tibia Plating System is intended for non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 21 1999

Ms. Angela J. Silvestri  
Manager, Regulatory Affairs  
Synthes (USA)  
1690 Russell Road  
P.O. Box 1766  
Paoli, Pennsylvania 19301

Re: K983787  
Trade Name: Synthes (USA) Proximal Tibia Plating System  
Regulatory Class: II  
Product Code: HRS  
Dated: October 26, 1998  
Received: October 27, 1998

Dear Ms. Silvestri:

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.

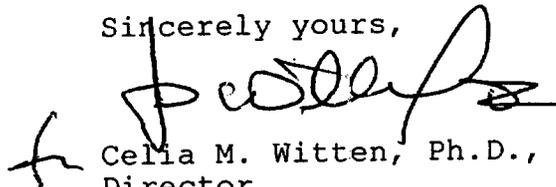
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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



1.0 Indications for Use Statement

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510(k) Number (if known): K983787

Device Name: Synthes (USA) Proximal Tibia Plating System

Indications for use:

The Proximal Tibia Plating System is intended for non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft 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 \_\_\_\_\_

(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K983787

Proximal Tibia Plating System 510(k)  
Synthes (USA)

Confidential

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