

**Section XII: 510(k) Summary of Safety and Effectiveness**

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

AUG 10 2005

**NAME OF FIRM:** I.T.S. Implantat-Technologie-Systeme GmbH  
Autal 28  
Lassnitzhoehe A – 8301  
AUSTRIA

**510(k) FIRM CONTACT:** Al Lippincott  
Engineering Consulting Services, Inc.  
3150 E. 200<sup>th</sup> St.  
Prior Lake, MN 55372

**TRADE NAME:** Pilonplate with Angular Stability

**COMMON NAME:** Bone Plate System

**CLASSIFICATION:** Plate, Fixation, Bone (see 21 CFR, Sec. 888.3030).

**DEVICE PRODUCT CODE:** HRS

**SUBSTANTIALLY EQUIVALENT DEVICES** Synthes Pilon Plate (**K020602**)  
DePuy/Ace TIMAX Pilon Plate (**K982347**)  
Synthes LCP Distal Tibia Plates (**K013248**)  
Synthes (USA) Medial Distal Tibia Plates (**K001945**)  
Link Small Bone Plates (May Anatomical Plate) (**K854825**)  
Zimmer Periarticular Plating System

**DEVICE DESCRIPTION:** The I.T.S. Pilonplate with Angular Stability is a low-profile universal left and right titanium 4, 6, and 8 hole plate with various length 4.2mm Cancellous self-tapping and head locking stabilization screws. Additional 4.5mm Cortical screws of various lengths are self-tapping and secure the Pilonplate to the shaft of the tibia bone. The Pilonplate is made from CP titanium according to ASTM F 67-00 and the screws are made from 6-4 alloyed titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

**INTENDED USE:** Indications for Use include fixation of complex intra- and extra- articular fractures, osteotomies, high medial malleolar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia.

**BASIS OF SUBSTANTIAL EQUIVALENCE:** The I.T.S. Pilonplate with Angular Stability is substantially equivalent to the Synthes, DePuy/ACE, Link America, and Zimmer bone plate systems.

**SUMMARY OF SAFETY AND EFFECTIVENESS:** The I.T.S. Pilonplate with Angular Stability is shown to be safe and effective for use in fracture fixation of the distal tibia in the leg.



AUG 10 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

I.T.X. Implantat-Technologie-Systeme GmbH  
c/o Mr. Albert Lippincott III  
U.S. Agent and Official Correspondent for I.T.S.  
Implantat-Technologie-Systeme GmbH  
Engineering Consulting Services, Inc.  
3150 E 200th Street  
Prior Lake, Minnesota 55372

Re: K052011

Trade/Device Name: Pilonplate with Angular Stability  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances  
and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: July 15, 2005  
Received: July 25, 2005

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

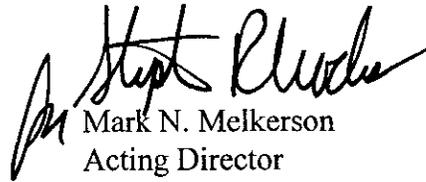
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) NUMBER: K052011DEVICE NAME: PILONPLATE WITH  
ANGULAR STABILITY

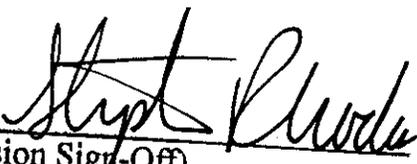
### INDICATIONS FOR USE:

The I.T.S. Pilonplate with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal tibia in the leg.

Indications for Use include fixation of complex intra- and extra-articular fractures, osteotomies, high medial malleolar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia.

Prescription Use X AND/OR Over-The-Counter-Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices, Office of CDRH, Office of Device Evaluation (ODE)

510(k) Number K052011