K051642

AUG 2 2 2005

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

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. 200th St.
Prior Lake, MN 55372

TRADE NAME: FR.O.H. Calcaneus Repair System

COMMON NAME: Bone Plate & Cannulated Cancellous Bone Screw System

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

Smooth or threaded metallic bone fixation fastener
(see 21 CFR, Sec. 888.3040)

DEVICE PRODUCT CODE: HRS & HWC

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes Locking Calcaneal Plates **(K991407)**
DePuy/Ace Calcaneal Peri-articular Plate **(K993465)**
Ace/DePuy Cannulated Cancellous Bone Screw **(K903810)**

DEVICE DESCRIPTION: The I.T.S. FR.O.H. Calcaneus Repair System is a combination of fracture reduction and alignment instrumentation with either calcaneus plate and/or cannulated cancellous screw fixation across calcaneal heel bone fracture site(s). The 15-hole Calcaneus Plate (universal left and right in 2 sizes) is made from CP titanium according to ASTM F 67-00 and corresponding plate locking and self-tapping 3.5 & 4.2mm Cancellous Screws from 6-4 alloyed titanium according to ASTM F 136-02. The fully threaded 7.3mm Cannulated Cancelous Screw is in various lengths from 50 to 90mm in 5mm increment sizes and is also made from 6-4 alloyed titanium according to ASTM F 136-02. All titanium plates and screws are surface conditioned with a TIODIZE, Type II preparation.

510(k) Summary of Safety and Effectiveness Continued:

INTENDED USE:	The I.T.S. FR.O.H. Calcaneus Repair System is used to stabilize a inta-articular and/or extra-articular fracture(s) and/or osteotomy of the calcaneus heel bone in the foot.
BASIS OF SUBSTANTIAL EQIVLAENCE:	The I.T.S. FR.O.H. Calcaneus Repair System Calcaneal Plate is substantially equivalent to the Synthes **(K991407)** and, DePuy/Ace **(K993465)** plating systems. The I.T.S. FR.O.H. Calcaneus Repair System Cannulated Cancellous Screw is substantially equivalent to the DePuy/Ace **(K903810)** cannulated screw system.
SUMMARY OF SAFETY AND EFFECTIVENESS:	The I.T.S. FR.O.H. Calcaneus Repair System is shown to be safe and effective for use in fracture fixation of the calcaneus heel bone in the foot.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

I.T.S. Implantat-Technologie-Systeme GmbH
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: K051642
Trade/Device Name: FR.O.H. Calcaneus Repair System
Regulation Number: 21 CFR 888.3030, 21 CRF 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: NDF, NDJ
Dated: June 10, 2005
Received: June 20, 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.

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,

Barbara Buehler for

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

Enclosure

i.T.S.
I.T.S. Implant-Technology-Systems GmbH
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Fax ++43 (0)316 211 21 20
office@its-implant.com

Indications for Use

510(k) NUMBER: _____

DEVICE NAME: **FR.O.H. Calcaneus Repair System**

INDICATIONS FOR USE:

The I.T.S. FR.O.H. Calcaneus Repair System is a titanium implant fracture fixation system for repairing fractures located in the calcaneus heel bone of the foot.

Indications for Use include: Intra and extra-articular fracture(s) of the calcaneus, corrective osteotomy, joint depression, non-displaced and tongue type, severely comminuted fractures, multifragmentary fractures, revision procedures, joint fusion, stabilization and fixation of fresh fractures, reconstruction of the calcaneus bones, and open and closed fractures of the calcaneus. The system can be used in both adult and pediatric patients.

This system is not intended for spinal use.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Barbara Brelin

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

n Sign-Off)

...sion of General, Restorative, Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

K051642