510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: I.T.S. GmbH
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

AUG - 5 2010

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

TRADE NAME: I.T.S. LRS Locking Reconstruction System

COMMON NAME: Bone Plate System

CLASSIFICATION: Plate, Fixation, Bone &

Smooth or threaded metallic bone fixation appliances and accessories.

(see 21 CRF, Sec. 888.3030 & Sec. 888.3040).

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: HWC

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes LISS (ALPS) System **(K961413)**
Stryker AxSOS Locked Plating System **(K061012)**
Smith&Nephew PERI-LOC Periarticular Locked Plate **(K092015)**
Zimmer Periarticular Locking Plates and Screws **(K070906)**
I.T.S. GmbH Straight Plate with Angular Stability **(K060156)**

DEVICE DESCRIPTION: The I.T.S. LRS (Locking Reconstruction System) consisting of the DFL (Distal Femur Locking) & PTL (Proximal Lateral Tibia Locking) are fracture fixation plating systems for repairing long bone factures located in the distal femur and proximal tibia in the human body. The DFL Plates consist of three plate lengths of 5, 9, & 13 hole pre-contoured shape in a left/right configuration to fit the distal femur and the PTL Plates consist of three plate lengths of 7, 12, & 17 hole precontoured shape in a left/right configuration to fit the proximal lateral tibia. Both plate systems are manufactured from Commercialy Pure (CP) Titanium material to allow for minor intra-operative forming/contouring by the surgeon. The plate design concept offers an extramedullary, internal fixation system, minimal bone contact, and a locked fixed-angle construct using angular stability locking screws into the plate. Both locking and non-locking high strength 6-4 Alloyed Titanium screws in a

5.9mm cancellous and 4.5mm cancellous/cortical sizes are offered. All screws are self-tapping for insertion into bone. The design intent of the aiming guide instrumentation allows the surgeon to prepare percutaneous targeting of screws through 'minimal invasive' stab incisions. This aiming guide instrument ensures that all targeted screws will be properly inserted and locked to the plate. The aiming guide instrumentation is radiolucent to allow offset (90 degree) fluroscopy evaluation in bone fragment reduction of the fracture site and confirmation of screw engagement into the plate. Small holes in the plate allow intermediate 'k-wire bone fracture segment positioning' for reducing and aligning the fracture bone segments while positioning the plate and the introduction of multiple sizes of locking/non-locking screws as needed for stabilizing the fracture – when using x-ray fluroscopy.

All I.T.S. LRS - DFL & PTL plates and screws are processed with a TIODIZE II surface treatment. A full compliment of instrumentation is available for use with the system.

INTENDED USE:

The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the distal femur and proximal lateral tibia of all pediatric patents (less than or equal to 21 years old) or adult patient.

Indications for Use include distal/proximal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the distal femur and proximal tibia.

The system(s) is not intended for spinal use.

EQUIVALENCE:

The I.T.S. LRS Locking Reconstruction System is substantially equivalent to the Synthes, Zimmer, Stryker, Smith & Nephew and I.T.S. GmbH bone plate systems. The Engineering Rationale is conclusive in showing greater size geometries, identical materials, and comparable 'Indications for Use' for the I.T.S. LRS – DFL & PTL plating systems in relation to the I.T.S. Straight Plate system (K060156).

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. LRS Locking Reconstruction System is shown to be safe and effective for use in fracture fixation of long bones in the distal femur and proximal tibia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Implantat-Technologie-Systeme Gmbh
% Engineering Consultant Services, Inc.
Mr. Al Lippincott
3150 East 200th Street
Prior Lake, Minnesota 55372

AUG - 5 2010

Re: K093868
Trade/Device Name: I.T.S. LRS Locking Reconstruction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: July 2, 2010
Received: July 6, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I.T.S.

K093868

Indications for Use

510(k) NUMBER: K093868

AUG - 5 2010

DEVICE NAME: **I.T.S. LRS Locking Reconstruction System**

INDICATIONS FOR USE:

The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the distal femur and proximal lateral tibia of all pediatric patients (less than or equal to 21 years old) or adult patient.

Indications for Use include distal/proximal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the distal femur and proximal tibia.

The 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)

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

K093868

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093868

Concurrence of CDRH, Office of Device Evaluation (ODE)

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