

**Section XII: 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.  
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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:** Epiphysis Screw

**COMMON NAME:** Cannulated Bone Screw

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

**DEVICE PRODUCT CODE:** HWC

**SUBSTANTIALLY EQUIVALENT DEVICES:** Synthes 6.5mm Cannulated Screw (**K021932**)  
Howmedica Osteonics ASNIS III Cannulated Screw (**K000080**)  
Orthomet/Wright Medical Cannulated Screw (**K862157**)  
Ace/Depuy Cannulated Self Tapping Cancellous Bone Screw (**K903810**)  
Zimmer MAGNA-Fx Cannulated Screw Fixation system  
Richards/Smith Nephew Universal Cannulated Screw  
DePuyAce ACE SCFE Screw

**DEVICE DESCRIPTION:** The I.T.S. Epiphysis Screw is a self-tapping and self-drilling screw with a cancellous thread that can be guided into a position via a guidewire pin. Screws are available partially threaded in lengths from 50mm to 120mm in 5mm increments. A full complement of instrumentation is available to assist in placement. The screws are manufactured from 6-4 ELI Titanium alloy with a Tiodize, Type II surface.

**INTENDED USE:** The I.T.S. Epiphysis Screw is used to stabilize a slipped capital femoral epiphysis and fracture fixation in the pelvis of large bones and large bone fragments. The system is not intended for spinal use.



FEB 24 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

I.T.S. Implant-Technologie-SystemeGMBH  
Al Lippincott  
Engineering Consulting Services, Inc.  
3150 E. 200th Street  
Prior Lake, Minnesota 55372

Re: K043410

Trade/Device Name: Epiphysis Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: December 10, 2004  
Received: December 10, 2004

Dear Mr. Al 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.

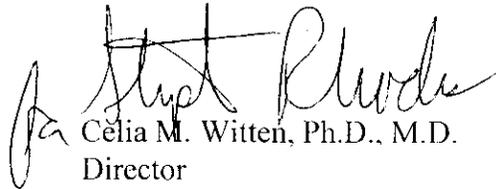
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Al Lippincott

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 "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

