Summary of Safety and Effectiveness for the T-Pin®

submitted by
Union Surgical, LLC
834 Chestnut Street
Philadelphia, PA 19107
Phone: (215)-521-3009

Contact Person: Al Weisenborn
Device Trade Name: T-Pin®
Common Name: Cannulated Fixation Screw
Classification Name: Smooth or threaded metallic bone fixation fastener per 21 CFR § 888.3040

Identification of a Legally Marketed Predicate Device

The Union Surgical, LLC T-Pin® is substantially equivalent to Taras Threaded Fixation Pin that is legally marketed and distributed by Union Surgical, LLC pursuant to K032532.

Device Description

The Union Surgical, LLC T-Pin® is a threaded and cannulated stainless steel Steinmann pin used for the repair of wrist fractures. The device incorporates a break-off shank. The device is optionally supplied with removal tools that permit pin extraction and a sterilization tray.

Intended Use

The Union Surgical, LLC implantable T-Pin® is intended for the repair of distal radius fractures, proximal ulna fractures, and comminuted wrist fractures without intraarticular fracture gapping.

Summary of Technological Characteristics

A 13-point comparison of technological characteristics of the Union Surgical, LLC T-Pin® and the Taras Threaded Fixation Pin was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The Union Surgical, LLC T-Pin® complies with the following standards, practices, and guidances:

- ASTM F366 – 82 (Reapproved 2000), Standard Specification for Fixation Pins and Wires

- ASTM F138 – 97, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical

The Union Surgical, LLC T-Pin® is substantially equivalent to Taras Threaded Fixation Pins that are legally marketed and distributed by Union Surgical, LLC. This has been demonstrated through a 13-point technological comparison of features and a 3-parameter comparison of mechanical performance.

The Implantable and tissue contact materials used to fabricate the T-Pin® and Instruments have a long history of safe usage in medical devices. Since the Union Surgical, LLC T-Pin® meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as, or better than, the predicate device. The T-Pin® will be manufactured per specifications using good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

John Taras, M.D.
President
Union Surgical, LLC
834 Chestnut Street, Suite G- 114
Philadelphia, PA 19107

Re: K053513
Trade/Device Name: T-Pin®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: December 12, 2005
Received: December 16, 2005

Dear Dr. Taras:

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,

for 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 (if known): K053513

Device Name: T-Pin®

Indications for Use:

The Union Surgical, LLC implantable T-Pin® is intended for the repair of distal radius fractures, proximal ulna fractures, and comminuted wrist fractures without intraarticular fracture gapping.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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