K112240 1/2

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5. 510(k) Summary

Manufacturer:	U & I Corporation 529-1, Yonghyun-dong, Uijungbu Kyunggi-Do, Korea 480-050 Gyeong-Je Kwon, Regulatory Affairs Specialist
Sponsor:	U & I Corporation 529-1, Yonghyun-dong, Uijungbu Kyunggi-Do, Korea 480-050
Sponsor Contact:	Gyeong-Je Kwon, Regulatory Affairs Specialist
Date Prepared:	August 01, 2011
Device Name:	Trade Name: *Dyna Locking Cannulated Screw™*
Common Name:	Bone Fixation Screws
Classification Name:	21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener
Product Code:	HWC – Screw, Fixation, Bone
Predicate Devices:	Richards Cannulated Screw (K951389) Synthes Cannulated Screw (K962823, K963192, K963172, K021932, K962011)

Description of Device:

The *Dyna Locking Cannulated Screw™* consists of various sizes of cannulated screws and washers. Cannulated screws are designed to be inserted over guide pins and provide several potential benefits over standard screws especially the precision with which they can be placed. Guide pins can be used for provisional fracture fixation, facilitating accurate fracture reduction before definitive fixation with screws. In addition, the guide pins can be placed percutaneously with potential benefits of decreased surgical morbidity. A washer may be used as an extension of the cannulated screw where the cortical bone is soft or thin.

All implants of *Dyna Locking Cannulated Screw™* are single use device, supplied

non-sterile and manufactured from titanium alloy(Ti-6Al-4V ELI) in accordance with ASTM F136. Specialized instruments made from surgical grade stainless steel are available for the instrumentation and removal of the *Dyna Locking Cannulated Screw™*.

Intended Use:

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures of the femur
- Tibial plateau fractures
- Fractures of the dorsal pelvic ring
- Pelvic sacroiliac joint disruption
- Ankle arthrodesis
- Other indications where cancellous screws are currently used and a guided system may be beneficial

Substantial Equivalence:

The *Dyna Locking Cannulated Screw™* is substantially equivalent to Richards Cannulated Screw(K951389) and Synthes Cannulated Screw(K962823, K963192, K963172, K021932, K962011) in design, material, mechanical performance, function and intended use. Engineering analyses of pull-out, bending, and torsional strength were conducted based on geometric/material comparison to predicate devices.

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

U & I Corporation
% Mr. Gyeong-Je Kwon
Regulatory Affairs Specialist
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

JAN - 4 2012

Re: K112240
Trade/Device Name: Dyna Locking Cannulated Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 16, 2011
Received: December 20, 2011

Dear Mr. Kwon:

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K112240

Device Name: *Dyna Locking Cannulated Screw™*

Indications for Use:

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures of the femur
- Tibial plateau fractures
- Fractures of the dorsal pelvic ring
- Pelvic sacroiliac joint disruption
- Ankle arthrodesis
- Other indications where cancellous screws are currently used and a guided system may be beneficial

Prescription Use ___X___ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

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

510(k) Number K112240