K092771

5. 510(k) Summary

U&I CORPORATION

DEC - 2 2009

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: September 2, 2009

Device Name: Trade Name: *Dyna Locking IM Nail™*

Common Name: Intramedullary Fixation System

Classification Name: Intramedullary Fixation Rod (HSB), per 21 CFR 888.3020

Product Code: HSB

Predicate Devices: Grosse & Kempf Locking Nail System (K860756)
Universal Tibial Nail and Unreamed Tibial Nail (K914453)
Osteo IC Nail (K933340)
Delta II Femoral Nail (K981529)
T2 Femoral Nail (K081152)

Description of Device:

The *Dyna Locking IM Nail™* consists of three types of intramedullary rods (Femoral Nail, Tibial Nail, Unreamed Tibial Nail), Locking Screw, and Nail Cap. The rods are available in a variety of diameters and lengths and have holes located at the proximal and distal ends for fixation to bone by means of locking screws. An Nail Cap screws into the threaded end of the nails to prevent bone ingrowth, otherwise newbone in the nail hamper to remove the nail.
All components of the *Dyna Locking IM Nail™* are single use device, supplied non-sterile and manufactured from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM 136.

Intended Use:

The *Dyna Locking IM Nail™* is intended to be implanted into the intramedullary canal of femur or tibia for alignment, stabilization, fixation of fractures caused by trauma or disease.

- Proximal, middle and distal third femoral and tibial shaft fractures
- Severely comminuted, spiral and segmental fractures
- Nonunions and malunions
- Bone lengthening

Substantial Equivalence:

The *Dyna Locking IM Nail™* is substantially equivalent to Grosse and Kempf Locking Nail System (K860756), Universal Tibial Nail and Unreamed Tibial Nail (K914453), Osteo IC Nail (K933340), Delta II Femoral Nail (K981529), T2 Femoral Nail (K081152) in design, performance, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 2 2009

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

Re: K092771
Trade/Device Name: Dyna Locking IM Nail™
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 2, 2009
Received: September 9, 2009

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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): K092771

Device Name: *Dyna Locking IM Nail™*

Indications for Use:

The *Dyna Locking IM Nail™* is intended to be implanted into the intramedullary canal of femur or tibia for alignment, stabilization, fixation of fractures caused by trauma or disease:

- Proximal, middle and distal third femoral and tibial shaft fractures
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- Nonunions and malunions
- Bone lengthening

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 MVM

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

510(k) Number K092771