K120419 (1/3)

MAY 2 1 2012

5. 510(k) Summary

U&I CORPORATION

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:	February 6, 2012
Device Name:	Trade Name: *Dyna Locking Ankle 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) T2 Ankle Arthrodesis Nail (K051590) Titanium Ankle Arthrodesis Nail (K021786)

Description of Device:

The *Dyna Locking Ankle Nail™* consists of Ankle Nail, Locking Screw, Set Screw, and End Cap. The Ankle nails are available in variety of diameters and lengths. And End Cap screws into the threaded end of the nail to prevent bone ingrowth. Locking Screw has the self-tap at the end of the screw.

All components of the *Dyna Locking Ankle Nail™* are single use device, supplied non-sterile, and manufactured from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM 136. Specialized instruments made from surgical instrument grade stainless steel are available for the instrumentation and removal of the *Dyna Locking Ankle Nail™*.

Intended Use:

The *Dyna Locking Ankle Nail*™ is used in various indications as follows.

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement of with an insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions requiring tibiocalcaneal arthrodesis
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Severe deformity as a result of talipes equionovarus, cerebral vascular accident, paralysis of other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint

Substantial Equivalence:

The *Dyna Locking Ankle Nail*™ is substantially equivalent to Grosse and Kempf Locking Nail System (K860756), T2 Ankle Arthrodesis Nail (K051590), Titanium Ankle Arthrodesis Nail (K021786) in design, performance, function and intended use.

1. Comparison Technological Characteristics

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similaritiesL\:

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The *Dyna Locking Ankle Nail*™ was tested in a non clinical setting (bench testing) to assess that no new safety and efficiency issues were raised with this device. The testing met all acceptance criteria and verifies that performance of the *Dyna Locking Ankle Nail*™ is substantially equivalent to the predicate devices.

The following tests were performed:

(1) Static test
- 4-point bend test of rod
- Torsion test of rod

(2) Dynamic test
- 4-point bend test of rod

3. Conclusion

The data and information provided in this submission support the conclusion that the *Dyna Locking Ankle Nail™* is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

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
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Republic of Korea 480-050

MAY 2 1 2012

Re: K120419
Trade/Device Name: Dyna Locking Ankle Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 6, 2012
Received: February 21, 2012

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/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,

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): K120419

Device Name: *Dyna Locking Ankle Nail™*

Indications for Use:

The *Dyna Locking Ankle Nail™* is used in various indications as follows.

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement of with an insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions requiring tibiocalcaneal arthrodesis
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- Severe deformity as a result of talipes equionovarus, cerebral vascular accident, paralysis of other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint

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)

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

510(k) Number K120419