DGIMED ORTHO

JAN - 6 2014

510(k) Summary
(Per 21 CFR 807.92(c))

Common/Usual Name:	DISTALOCK™ Tibial Intramedullary Nail System
Product Trade Name:	DISTALOCK™ Tibial Intramedullary Nail System
Classification Name:	Rod, Fixation, Intramedullary and Accessories Class II per 21 CFR § 888.3020 Product Code HSB
Predicate Device:	Smith & Nephew TriGen Tibial Nail System K051557
Manufacturer:	DGIMED Ortho, Inc. 12400 Whitewater Drive, Suite 2010 Minnetonka, MN 55343
Contact:	Scott Youngstrom VP of Finance, Chief Operating Officer
Date Prepared:	September 5, 2013

Device Description:

The DGIMED Ortho DISTALOCK™ Tibial Intramedullary Nail System permits an intramedullary approach for fixation of fractures of the tibia. The DISTALOCK™ Tibial Nail is a closed section, cannulated, curved intramedullary fixation device containing four proximal (three static and one dynamic) and three distal holes to accept locking screws which thread transversely though the proximal and distal third of the tibia. The DISTALOCK™ Tibia Intramedullary Nail System includes the following components: DISTALOCK™ Tibial Intramedullary nails, locking screws and end caps made of titanium alloy. The DISTALOCK™ Tibial Ancillary Instrumentation includes the DISTALOCK™ Tibial Drill and other disposable and reusable instruments needed for accessing the tibial medullary canal; preparing the bone for placement and installation of the nail and locking screws; and removal of the nail and locking screws if required.

DGIMED ORTHO

Indications for Use:

The DISTALOCK Tibial IM Nail System is intended to stabilize shaft fractures between the proximal and distal third of the tibia. Indications include transverse, comminuted, spiral, oblique, and segmental fractures. The Tibial Nail may also be used for treatment of mal-unions as well as prophylactic nailings of impending pathological fractures

Substantial Equivalence Comparison:

Results of design verification and validation testing demonstrate that the DISTALOCK™ Tibial Intramedullary Nail System is as safe as the predicate device. The risk assessment results, together with the results of design verification and validation testing presented in this submission, confirm that the DISTALOCK™ Tibial Intramedullary Nail System raises no new questions of safety or effectiveness compared to the predicate device. The DISTALOCK™ Tibial Intramedullary Nail System has been shown to be substantially equivalent to the legally marketed device for the purpose of 510(k) clearance.

Summary of Non-Clinical Testing:

The biological safety of the DISTALOCK™ Tibial Intramedullary Nail System was achieved through the selection of materials that demonstrated appropriate levels of biocompatibility. Human factor analysis was conducted and concluded that the DISTALOCK™ Tibial Intramedullary Nail System presented acceptable human factors features in both the functioning of the device and usage of the labeling. Bench testing and cadaver testing were conducted to ensure the performance and safety of the DISTALOCK™ Tibial Intramedullary Nail System and to demonstrate substantial equivalency to the predicate device.

No new risks or efficacy concerns other than those identified with the predicate device were raised. Results of non-clinical testing demonstrated that the DISTALOCK™ Tibial Intramedullary Nail System is safe and effective for its intended use.

Conclusion:

The DISTALOCK™ Tibial Intramedullary Nail System has similar intended use, material biosafety profile, and technical characteristics as the predicate device. Non-clinical testing was conducted to verify the safety and performance of the DISTALOCK™ Tibial Intramedullary Nail System and to ensure the device functions as intended and meets design specifications. As a result, the DISTALOCK™ Tibial Intramedullary Nail System has been demonstrated to be substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 6, 2014

DGIMED Ortho, Incorporated
Mr. Scott Youngstrom
Vice President of Finance, Chief Operating Officer
12400 Whitewater Drive, Suite 2010
Minnetonka, Minnesota 55343

Re: K132830
Trade/Device Name: DISTALOCK™ Tibial Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 4, 2013
Received: November 14, 2013

Dear Mr. Youngstrom:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lori A. Wiggins

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

Enclosure

5.0 INDICATION FOR USE STATEMENT

510(k) Number (if known): Not Yet Assigned K132830

Device Name: DISTALOCK™ Tibial Intramedullary Nail System

Indications for Use:

Intended to stabilize shaft fractures between the proximal and distal third of the tibia. Indications include transverse, comminuted, spiral, oblique, and segmental fractures. The Tibial Nail may also be used for treatment of mal-unions as well as prophylactic nailings of impending pathological fractures.

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 Center for Devices and Radiological Health (CDRH)

Page 1 of 1

Casey E. Hanley, Ph.D.
Division of Orthopedic Devices