

**510(k) Summary**  
(per 21 CFR 807.87(h))

APR 20 2010

**Common/Usual Name:** Intramedullary Fixation Rod and Accessories

**Product Trade Name:** DISTALOCK™ Femoral Intramedullary Nail System

**Classification Name:** Rod, Fixation, Intramedullary and Accessories  
Class II per 21 CFR § 888.3020  
Product Code HSB

**Predicate Device:** DGIMED Ortho Inc. Revolution™ Femoral Intramedullary Nail System K091309

**Manufacturer:** DGIMED Ortho, Inc.  
12400 Whitewater Drive, Suite 2010  
Minnetonka, MN 55343

**Contact:** Scott Youngstrom  
VP of Finance, Chief Operating Officer

**Date Prepared:** February 3, 2010

**Device Description:**

The DISTALOCK™ Femoral Intramedullary (IM) Nail System permits an antegrade intramedullary approach for fixation of fractures of the femur. The DISTALOCK™ Femoral Intramedullary Nail is a closed section, cannulated, thick walled, mirror finished, curved intramedullary fixation device containing two proximal and two distal holes to accept locking screws which thread transversely through the proximal and distal third of the femur. The DISTALOCK™ Femoral IM Nail System includes the following components: DISTALOCK™ IM standard entry and trochanteric nails, locking screws and end caps made of titanium alloy. The DISTALOCK™ Ancillary Instrumentation includes the DISTALOCK™ drill, the DISTALOCK™ Control System (which includes the control box, drill motor assembly and hand controller) and other disposable and reusable instruments.

**Indications for Use:**

The DISTALOCK™ Femoral IM Nail System is indicated for use in orthopedic intramedullary nailing procedures: midline femoral fractures, femoral fractures in multiple trauma patients, fractures in the morbidly obese patient, fractures in osteoporotic bone or malunions and nonunions.

**Substantial Equivalence Comparison:**

Results of design verification and validation testing demonstrate that the device system as modified 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™ Femoral IM Nail System, as modified, raises no new questions of safety or effectiveness compared to the predicate device. The DISTALOCK™ Femoral IM 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™ Femoral IM 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™ Femoral IM 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™ Femoral IM Nail System and to demonstrate substantial equivalent to 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™ Femoral Intramedullary (IM) Nail System is safe and effective for its intended use.

**Conclusion:**

The DISTALOCK™ Femoral IM 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™ Femoral IM Nail System and to ensure the device functions as intended and meets design specifications. As a result, the DISTALOCK™ Femoral IM Nail System has been demonstrated to be substantially equivalent to the predicate device and is safe and effective for its intended use.



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

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

APR 20 2010

Re: K100312

Trade/Device Name: DISTALOCK™ Femoral Intramedullary Nail System  
Regulation Number: 21 CFR 888.3020  
Regulation Name: Intramedullary Fixation Rod  
Regulatory Class: II  
Product Code: HSB  
Dated: March 30, 2010  
Received: April 1, 2010

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.

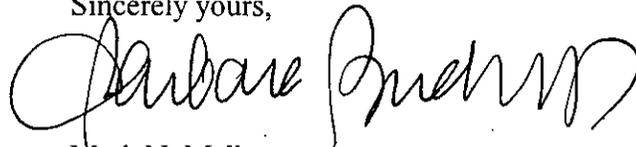
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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

Current 510(k) Number: K100312

**Device Name:**

DISTALOCK™ Femoral Intramedullary Nail System

**Indications for Use:**

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Prescription Use              
(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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100312