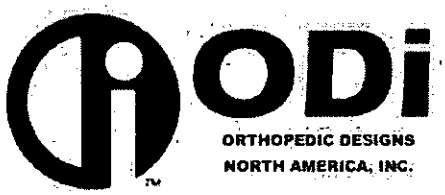
AUG 2 2 2011

SECTION 5: 510(k) SUMMARY

K111352
1 of 2



Date of Preparation: May 12, 2011

Company Name / Contact:

Company: Orthopedic Designs North America, Inc. (ODi-NA)
5912 Breckenridge Parkway
Suite F
Tampa, FL 33610

Contact: Seth Masek
Phone: (813) 443-4905
Fax: (888) 632-8047

Device Identification:

Proprietary Name:	Talon™ DistalFix™ Proximal Femoral Nail
Common Used Name:	Femoral Nail
Classification Name:	Rod, Fixation, Intramedullary and Accessories
Classification Reference:	21 CFR § 888.3020
Classification Panel:	87 – Orthopedic Devices
Device Product Code:	HSB
Proposed Regulatory Class:	Class II

Device Description:

The Talon™ DistalFix™ Proximal Femoral Nail is used for fixation and stabilization of fractures of the proximal femur until bony union can occur. The system consists of the following parts:

- A **femoral nail** with a proximal portal for passage of a lag screw and distal portals that allow passage of deployable integral talons to achieve distal fixation from within the intramedullary canal. The distal talons may be retracted for removal of the intramedullary nail if and when it is necessary. The nail will be provided in a pre-assembled condition with the deployable distal nail talons, distal end cap and integral lock screw subassembly already installed.
- A **Talon™ lag screw** with proximal portals for passage of deployable talons to increase the purchase of the lag screw within the femoral neck/head. These talons may also be retracted for removal of the lag screw if and when it is necessary. The lag screw is cannulated and keyed with tapered flats on the distal end. This keyed shaft allows the option of static, compression, or axial

translation fixation types of the fracture fragments while mitigating proximal migration and rotation of the lag screw. The lag screw will be provided in a pre-assembled condition with the deployable talons and end cap already installed. A similar Talon™ lag screw was previously cleared in 510(k)s K014189 and K033286.

- A **proximal end cap** will be provided separately. The end cap prevents bony ingrowth and preserves the threads which may be used for attachment of instrumentation during explantation of the nail.

ODi-NA will manufacture the implants from implant grade titanium alloy.

Indications for Use:

The Talon™ DistalFix™ Proximal Femoral Nail's primary indications are for fixation/stabilization of stable and unstable fractures of the proximal femur including intertrochanteric fractures, pertrochanteric fractures, high subtrochanteric fractures (without shaft extension), and combinations of these fractures. The long nail allows the additional indication of low subtrochanteric fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

Substantial Equivalence Information:

Orthopedic Designs North America, Inc. believes the Talon™ DistalFix™ Proximal Femoral Nail is substantially equivalent to the products described herein with respect to indications for use, device design, materials, method of manufacture and method of sterilization. Within the proposed class, the following devices are used as predicate devices for comparison: Stryker® Gamma3™ Nail System (K043431, K034002, K032244), Orthopedic Designs (ODi) Talon™ Intramedullary Hip Nail (K014189), and Orthopedic Designs (ODi) Talon™ Long Proximal Femoral Nail System (K033286).

Mechanical Data:

Review of the mechanical test data indicates the Talon™ DistalFix™ Proximal Femoral Nail is substantially equivalent to the previously cleared ODi nails (K033286 and K014189).

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

Orthopedic Designs North America, Inc. (ODi-Na)
% Mr. Seth Masek
5912 Breckenridge Parkway, Suite F
Tampa, Florida 33610

AUG 2 2 2011

Re: K111352
Trade/Device Name: Talon™ DistalFix™ Proximal Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Masek:

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,

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

Enclosure

SECTION 4: DEVICE INDICATIONS FOR USE

510(k) Number (if known): K111352

Device Name: Talon™ DistalFix™ Proximal Femoral Nail System

Indications for Use:

The Talon™ DistalFix™ Proximal Femoral Nail's primary indications are for fixation/stabilization of stable and unstable fractures of the proximal femur including intertrochanteric fractures, pertrochanteric fractures, high subtrochanteric fractures (without shaft extension), and combinations of these fractures. The long nail allows the additional indication of low subtrochanteric fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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

510(k) Number K111352