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SECTION 12: 510(k) SUMMARY

K014189

ODi ORTHOPEDIC DESIGNS, INC.

Premarket Notification

510(k) Summary of Safety and Effectiveness Information

For Release Upon Request Only

Date of Preparation: December 20, 2001

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: Orthopedic Designs, Inc. (ODi)
6965 1st Ave. North
St. Petersburg, FL 33710

Contact: John Sodeika
(727) 343-0338

Establishment Registration Number: 1064129

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

Device Description:

The ODi Talon™ Intramedullary Hip 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:

- An **intramedullary nail** with portals that allow passage of distal cortical screws and a proximal lag screw assembly. The nail will be provided in a pre-assembled condition with the sleeve lock and end cap already attached to save time in surgery.
- The **Talon™ Lag Screw** is completely compatible with ODi's Talon™ Compression Hip Screw system and has been previously approved by the FDA in K984331. The Talon™ lag screw has deployable tangs to increase the purchase of the lag screw within the femoral neck/head. These tangs may also be retracted for removal of the lag screw if and when it is necessary. The distal end of the lag screw is keyed with a "double-d" shape, cannulated and internally threaded. This keyed shaft provides rotational stability for better lag screw purchase. The screw is internally threaded to allow the use of the compression screw to compress the fracture fragments.
- A **slotted sleeve** which passes through the intramedullary nail. The sleeve is keyed to the lag screw assembly to prevent its rotation while allowing axial translation of the lag screw.
- A **sleeve lock** which passes through the proximal end inner bore of the intramedullary nail. The sleeve lock has 2 positions within the intramedullary nail - "locked" and "unlocked". In the "locked" position, the legs on the sleeve lock mate with the slots in the sleeve thereby preventing rotation and axial translation of the sleeve, but allowing axial translation of the lag screw assembly. The sleeve lock is provided for surgery pre-assembled in the "unlocked" position within the intramedullary nail.
- A **compression screw** which shoulders against the slotted sleeve and engages the internal threads in the distal end of the lag screw assembly providing for axial compression of a proximal hip fracture. A polyethylene patch is embedded in the threaded portion of the compression screw to prevent rotation of the screw inside the lag screw after the desired amount of compression is reached.. The compression screw is used to compress the fracture site by drawing the nail and lag screw portions together. The compression screw has been previously approved by the FDA in K984331.
- An **end cap** with both internal and external threads and a keying slot. The external threads engage the internal threads in the proximal end of the intramedullary nail and protect them from bony ingrowth for the possible future attachment of nail removal instrumentation for explantation. The internal threads in the end cap mate with the nail installation instrumentation. The end cap is provided for surgery pre-assembled in the intramedullary nail.
- **Cortical screws** are provided to cross-lock the distal end of the nail to the femoral shaft to help prevent axial translation or rotation of the nail. The cortical screws have been previously approved by the FDA in K984331.

The nail will be provided in a pre-assembled condition with the sleeve lock and end cap already attached to save time in surgery.

ODi will manufacture the implants from implant grade stainless steels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Mr. John Sodeika
Vice President of Engineering Operations
Orthopedic Designs, Inc.
6965 1st Avenue N.
St. Petersburg, Florida 33710

Re: K014189
Trade/Device Name: Odi Talon™ Intramedullary Hip Nail
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDS
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Sodeika:

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.

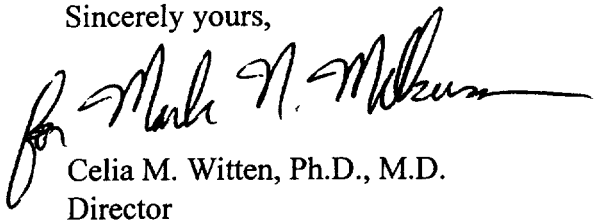
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5: DEVICE INDICATIONS FOR USE

510(k) Number:

Device Name: ODi Talon™ Intramedullary Hip Nail

Indications For Use:

The ODi Talon™ Intramedullary Hip Nail will be used on indications that are common with presently marketed intramedullary hip nail systems. The primary indications are for fixation/stabilization of stable and unstable fractures of the proximal femur including intertrochanteric fractures, pertrochanteric fractures, high subtrochanteric fractures, and combinations of these fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

Contra-Indications:

The ODi Talon™ Intramedullary Hip Nail is not intended for use in patients with the following conditions:

1. Active local Infection.
2. Metal sensitivity or allergic reaction to foreign bodies.
3. Loss of bone stock or insufficient bone quality to support the device.
4. Obliterated medullary canal.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109) X OR Over-The-Counter _____

for Mark N Milleresen

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014189

(Optional Format 1-2-96)