

JAN 12 2004

K033286

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SECTION 12: 510(k) SUMMARY



Premarket Notification

510(k) Summary of Safety and
Effectiveness Information

For Release Upon Request Only

Date of Preparation: October 6, 2003

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: Orthopedic Designs, Inc. (ODi)
9521 International Court North
St. Petersburg, FL 33716

Contact: John Sodeika
(727) 570-9200

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™ Long 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 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** used in the nail system 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. The compression screw is used to compress the fracture site by drawing the nail and lag screw portions together. The cortical screws have 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.

Indications for Use:

The ODi TALON™ Long Proximal Femoral 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, subtrochanteric fractures, and combinations of these fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

Contra-indications for Use:

The ODi TALON™ Long Proximal Femoral 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.

Substantial Equivalent Devices:

Orthopedic Designs, Inc. believes the ODi TALON™ Long 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:

Smith & Nephew Richards - Intramedullary Hip Screw	(K895241, K912162, K921786, K954712)
Howmedica - Gamma Locking Nail System	(K893639, K972813, K944883)
Orthopedic Designs - TALON™ Intramedullary Hip Nail	(K014189)
Orthopedic Designs - TALON™ Compression Hip Screw	(K984331)

Each of these products is commercially available and are marketed Class II devices indicated for similar use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Sodeika
Vice President of Engineering Operations
Orthopedic Designs, Inc.
9521 International Court N
St. Petersburg, Florida 33716

Re: K033286

Trade/Device Name: ODi TALON™ Long Proximal Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: October 7, 2003
Received: October 14, 2003

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.

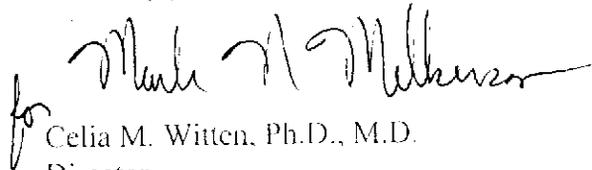
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. John Sodcika

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name.

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: K03 3286

Device Name: ODi TALON™ Long Proximal Femoral Nail System

Indications For Use:

The ODi TALON™ Long Proximal Femoral Nail's primary indications are for fixation/stabilization of stable and unstable fractures of the proximal femur including intertrochanteric fractures, pertrochanteric fractures, 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™ Long Proximal Femoral 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 X OR Over-The-Counter
(per 21 CFR 801.109)

for Mark A. Melkerson
Division Signatory
Executive
Orthopedic Devices

(Optional Format 1-2-96)

510(k) Number K033286 5-1