



February 22, 2018

Orthopedic Designs North America, Inc.  
Robin Wilson  
Quality Manager  
5912 Breckenridge Parkway, Suite F  
Tampa, Florida 33610

Re: K173255

Trade/Device Name: Talon™ DistalFix™ Humeral Nail  
Regulation Number: 21 CFR 888.3020  
Regulation Name: Intramedullary fixation rod  
Regulatory Class: Class II  
Product Code: HSB  
Dated: January 25, 2018  
Received: January 26, 2018

Dear Ms. Wilson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Katherine D. Kavlock -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2020  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K173255

Device Name

Talon™ DistalFix™ Humeral Nail

Indications for Use (Describe)

The Talon™ DistalFix™ Humeral Nail System is indicated to aid in the alignment and stabilization of humeral fractures, including:

- Diaphyseal fractures of the humeral shaft
- Proximal humeral fractures with diaphyseal extension
- Impending pathologic fractures

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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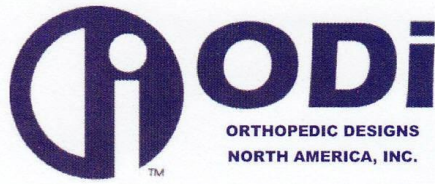
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## **SECTION 5: 510(k) SUMMARY**



**Date of Preparation:** January 25, 2018

**Company Name / Contact:**

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

Contact: Robin Wilson  
Phone: (888) 635-8535  
Fax: (888) 632-8047

**Device Identification:**

Proprietary Name:	Talon™ DistalFix™ Humeral Nail
Common Used Name:	Humeral 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™ Humeral Nail System is used to aid in the alignment and stabilization of humeral fractures. The system consists of the following parts:

- A **humeral nail** with proximal portals for passage of cortical locking screws 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 and distal end cap already installed.
- **Cortical locking screws** will be provided separately. The cortical locking screws have a reduced minor diameter at the tip which provides increased

- purchase in cancellous bone by increasing the thread height and are provided for proximal fixation if desired.
- 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™ Humeral Nail System is indicated to aid in the alignment and stabilization of humeral fractures, including: diaphyseal fractures of the humeral shaft; proximal humeral fractures with diaphyseal extension; and impending pathologic fractures.

**Substantial Equivalence Information:**

Orthopedic Designs North America, Inc. believes the Talon™ DistalFix™ Humeral 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 device is used as a predicate device for comparison: Synthes® Titanium Cannulated Humeral Nail Expert System (K033071).

**Performance Data:**

Review of the mechanical test data and supporting engineering analysis demonstrates the Talon™ DistalFix™ Humeral Nail System is substantially equivalent to the previously cleared Synthes® Titanium Cannulated Humeral Nail Expert System (K033071). Pyrogen testing was performed in accordance with ANSI/AAMI ST72 and confirmed the implants meet the specified endotoxin limit of 20.0 USP Endotoxin Units per device using the *Limulus* amoebocyte lysate (LAL) test.