November 5, 2024

Orthopedic Designs North America, Inc. (ODI-NA)
Robin Wilson
Quality Manager
5912 Breckenridge Parkway, Suite F
Tampa, Florida 33610

Re: K241484
Trade/Device Name: Atlas™ Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 24, 2024
Received: October 8, 2024

Dear Robin 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.11.05 11:15:46 -05'00'

for: Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241484

Device Name

Atlas™ Humeral Nail System

Indications for Use *(Describe)*

The Atlas™ 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.

510(k) #: K241484

510(k) Summary

Prepared on: 2024-11-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Orthopedic Designs North America, Inc. (ODI-NA)
Applicant Address	5912 Breckenridge Parkway, Suite F Tampa FL 33610 United States
Applicant Contact Telephone	8134434905
Applicant Contact	Ms. Robin Wilson
Applicant Contact Email	rwilson@odi-na.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Atlas™ Humeral Nail System
Common Name	Rod, Fixation, Intramedullary And Accessories
Classification Name	Intramedullary fixation rod
Regulation Number	888.3020
Product Code(s)	HSB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173255	Talon™ DistalFix™ Humeral Nail	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The Atlas™ 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/or Atlas™ Screws. The humeral nail also has 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 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.
- Atlas™ Screws will be provided separately. The Atlas™ Screws have distal portals that allow the passage of integral talons that can be deployed for additional fixation and stability.
- 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. The proximal end cap also comes in a locking version which includes a distal shaft that locks the cortical locking screw or Atlas™ screw placed in the most proximal portal.

ODI-NA will manufacture the implants from implant grade titanium alloy (Ti-6AL-4V-ELI) per ASTM F136. The implants will be offered in both sterile (steam) and non-sterile packaging configurations and are intended for single-use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Atlas™ 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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same between the subject device and the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Atlas™ Humeral Nail System is substantially equivalent to the predicate device in which the intended use, materials, sterility, principle of operation and indications for use are identical. There are minor differences in technological characteristics between the subject device and predicate device regarding:

- Proximal diameter
- Number and orientation of proximal screw portals
- Screw size
- Addition of Atlas™ screw

These minor differences do not raise different questions of safety or effectiveness and substantial equivalence is demonstrated through the testing described below.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following nonclinical performance tests were performed to demonstrate substantial equivalence to the predicate:

- Engineering analysis of humeral nails considering:
  - o Four-point bending strength
  - o Torsional strength
- Bending fatigue test of Atlas™ Screws per ASTM F1264-16
- Bending fatigue test of Locking Screws per ASTM F1264-16
- Testing of Atlas™ Screws per ASTM F543
- Testing of Locking Screws per ASTM F543
- Cyclic loading of implanted Talons
- Cyclic loading of implanted Atlas™ Screws with Talons deployed

The totality of data collected through performance testing and analysis has successfully demonstrated the Atlas™ Humeral Nail System is substantially equivalent to the previously cleared predicate device currently marketed for the same intended use.