DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2014

Trumed Group, LLC
% Ms. Rhonda Alexander
Senior Regulatory Specialist
Registrar Corporation
144 Research Drive
Hampton, Virginia 23669

Re: K133166
Trade/Device Name: Ins Hilden Tibial Arzzt
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 10, 2014
Received: October 14, 2014

Dear Ms. Alexander:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins -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

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133166

Device Name
Ins Hilden Tibial Arzzt

Indications for Use *(Describe)*
Ins Hilden Tibial Arzzt is intended to stabilize fractures of the tibial shaft; open and closed tibial shaft fractures; and tibial malunion and non-unions.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Premarket Notification 510(k) Summary

| | | |
|---|---|---|
| 1. | Submitter's Name: | Trumed Group LLC |
| 2. | Contact Person: | Jorge Trujillo Zavala<br>600 Kenrick C-32<br>Houston, Texas 77060<br>281 847 4098 (phone) |
| 3. | Date Prepared: | August 13, 2013 |
| 4. | Device Name: | Ins Hilden Tibial Arzzt |
| 5. | Common Name: | Intramedullary Nail and Locking Screws |
| 6. | Classification Name: | Intramedullary Fixation Rod |
| 7. | Product Code: | HSB |
| 8. | Device Classification: | Class 2 |
| 9. | Regulation Number: | 21 CFR 888.3020 |
| 10. | Predicate Devices: | Synthes (USA)<br>Universal Tibial Nail and Unreamed Tibial Nail<br>**K914453**<br><br>Synthes (USA)<br>Ti-6al-7nb Urtn<br>**K932330** |

11. Device Description:

The Ins Hilden Tibial Arzzt is a single use system that consist the following components:

- The Tibial Nail: a solid nail, with four orifices, two for distal locking and two for the proximal locking. One of the orifices on the proximal locking is for static locking and one for dynamic locking. Also the nail is milled on the distal end and flat at the proximal end with a threaded insertion/extraction hole.

- Locking Screws with conical head and self-tapping on the head and blunt.
- End caps.

12. Intended Use: Ins Hilden Tibial Arzzt is intended to stabilize fractures of the tibial shaft; open and closed tibial shaft fractures; and tibial malunion and non-unions.

13. Standards

**ASTM F 983-86 (Reapproved 2009)**. Standard Practice for Permanent Marking of Orthopedic Implant Components

**ASTM F1264-03 (Reapproved 2007)**. Standard Specification and Test Methods for Intramedullary Fixation Devices

**ISO 5832-03:1996**. Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminum 4-vanadium alloy

The Ins Hilden Tibial Arzzt has met the requirements of the above standards.

14. Comparison of Technological Characteristics and Substantial Equivalence

The Ins Hilden Tibial Arzzt has similar intended use, target population, anatomical sites, materials, biocompatibility as the Ti-6al-7nb Urtn and the UTN.

The engineering analysis comparing the static bending and static torsional yield strengths of the Ins Hilden Tibial Arzzt 8 mm Tibial Nail to the Synthes UTN 8 mm demonstrates that the performance and properties of Ins Hilden Tibial Arzzt are substantially equivalent to the predicate device.

Test Performed

According the ASTM F-1264: Standard Guide for Mechanical Performance Considerations for Intramedullary Fixation Devices, our system was tested and met the requirements in the following categories:

- Static Testing
- Torsion Testing
- Fatigue Testing

Also, we performed an engineering analysis comparing the static bending and static torsional yield strengths of the Ins Hilden Tibial 8 mm Tibial Nail to the Synthes UTN 8 mm proving to be as strong as the predicate device.