Truemed Group LLC
Nina Galeana Rodriguez
Coordinator
2002 Timberloch Place Suite 200
The Woodlands, Texas 77380

January 16, 2018

Re: K172189
Trade/Device Name: Ins Hilden Humeral Arzzt, Ins Hilden Cannulated Tibial Arzzt, Ins Hilden Femoral Arzzt & Ins Hilden Retrograde Femoral Arzzt
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 12, 2017
Received: December 14, 2017

Dear Ms. Nina Galeana Rodriguez:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

TRUEMED GROUP
2002 Timberloch Pl Suite 200
The Woodlands, Texas 77380

Indications for Use

510(k) Number (if known): K172189

Device Name:

Ins Hilden Humeral Arzzt, Ins Hilden Cannulated Tibial Arzzt, Ins Hilden Femoral Arzzt & Ins Hilden Retrograde Femoral Arzzt.

Indications for use:

Ins Hilden Arzzt Nail Systems, consisting of intramedullary solid and cannulated nails, end cap and locking screws, are intended for fixation of fractures of different types: of the shaft, open and closed shaft fractures; and malunion and non-unions of the Femur, Tibia, and Humerus.

Prescription Use: ___X____ AND/OR Over-The-Counter Use: _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Premarket Notification 510(k) Summary

1. Submitter's Name: Trumed Group LLC
2. Contact Person: Jorge Trujillo Zavala
   2002 Timberloch Pl Suite 200
   The Woodlands, Texas 77380
   Phone 832 442 2310
3. Date Prepared: June 5, 2017
4. Device Name: Ins Hilden Humeral Arzzt, Ins Hilden Cannulated Tibial Arzzt, Ins Hilden Femoral Arzzt & Ins Hilden Retrograde Femoral Arzzt.
5. Common Name: Rod, Fixation, Intramedullary and Accessories
6. Classification Name: Rod, Fixation, Intramedullary and Accessories per 21 CFR section 888.3020.
7. Product Codes: HSB
8. Devices Classification: Class II
9. Regulation Numbers: 21 CFR 888.3020.
10. Predicate Devices: Ins Hilden Tibial Arzzt K133166
    DEPUY ACE Antegrade Retrograde Humeral Nail System K033878
    DEPUY ACE VERSANAIL TIBIAL NAIL K032097
    T2 Femoral Nail (K010801)
    ARZZT 3.5/4.5 Small and Large Fragment System (K162507)
    Devices Description:
    I. The **Ins Hilden Humeral Arzzt** is a single use system that consist the following components:

    i. Nail, is solid and cannulated, with five orifices, two for distal locking and three 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.

ii. End caps.

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

The system is manufactured from titanium alloy Ti6Al4V, a medical-grade material that is recognized as generally accepted for the manufacture of implants for their level of biocompatibility with surrounding tissues. It is intended to be used in adult men and women, and implanted during surgeries performed in hospitals.

II. The **Ins Hilden Femoral Arzzt** is a single use system that consist the following components:

i. Nail, is solid and cannulated 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.

ii. End caps.

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

The system is manufactured from titanium alloy Ti6Al4V, a medical-grade material that is recognized as generally accepted for the manufacture of implants for their level of biocompatibility with surrounding tissues. It is intended to be used in adult men and women, and implanted during surgeries performed in hospitals.

III. The **Ins Hilden Femoral Retrograde Arzzt** is a single use system that consist the following components:

i. Nail, is solid and cannulated, with five orifices, two for distal locking and three for the proximal locking. All three proximal orifices for static locking. Also the nail is milled on the distal end and flat at the proximal end with a threaded insertion/extraction hole.

ii. End caps.

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

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

i. Nail, is cannulated, with four orifices, two for distal locking and four for the proximal locking. All three proximal orifices for static locking. Also the nail is milled on the distal end and flat at the proximal end with a threaded insertion/extraction hole.

ii. End caps.

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

The system is manufactured from titanium alloy Ti6Al4V, a medical-grade material that is recognized as generally accepted for the manufacture of implants for their level of biocompatibility with surrounding tissues. It is intended to be used in adult men and women, and implanted during surgeries performed in hospitals.

11. Intended Uses: Ins Hilden Arzzt Nail Systems, consisting of intramedullary solid and cannulated nails, end cap and locking screws, are intended for fixation of fractures of different types: of the shaft; open and closed shaft fractures; and malunion and non-unions of the Femur, Tibia, and Humerus.

12. Analysis Performed: We performed engineering analyses comparing the static bending and

static torsional yield of the predicate devices with the subject devices confirming substantial equivalence within them.

13. Standards:

• ASTM F-136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.
• ASTM F-983-86 Standard Practice for Permanent Marking of Orthopedic Implant Components
• ISO 5832-3:1996. Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
The Ins Hilden Nails Arzzt Systems met the requirements of the above standards.

15. Substantial Equivalence:

Comparing the INS HILDEN HUMERAL ARZZT, INS HILDEN CANNULATED TIBIAL ARZZT, INS HILDEN FEMORAL ARZZT, and the INS HILDEN FEMORAL RETROGRADE ARZZT systems with the PREDICATE DEVICES (K133166, K033878, K032097) which have the device names in order shown INS HILDEN TIBIAL ARZZT, DEPUY ACE Antegrade Retrograde Humeral Nail System, T2 Femoral Nail (K010801) and ARZZT 3.5/4.5 Small and Large Fragment System (K162507) we found the following conclusion:

SUBSTANTIAL EQUIVALENCE CONCLUSION

SIMILARITIES

Intended Uses: Stabilization of fractures, osteotomies and non-unions of long bones.

Fixation: Once the nail is inside the bone, the fixation of the fracture is the same, since the limb is immobilized.

Types of fractures: Closed and open fractures type A, B and C from AO classification.

- Target Population: Men and Women in adulthood.
- Material: Same Titanium alloy Ti6Al4V
- Implant technique: All nails use the same principle of attaching to a

modular assembly to insert the nail.

PERFORMANCE

All systems are intended for fixation of fractures, of long bones, closed and open fractures type A, B and C from AO classification, with delay or without consolidation and bones osteotomies and non-unions.

With similar clinical, the patients had no complications with either system during the healing process, after the reduction and fixation of the fracture with the subject devices, we can conclude substantial equivalence between the predicate K133166 Ins Hilden Tibial Arzzt and the subject devices.

According to the engineering analysis, the subject devices are stronger when applying the same force than the predicate devices K033878, K032097, K010801 which has the device name in the same order as shown, DEPUY ACE Antegrade Retrograde Humeral Nail System, DEPUY ACE VERSANAIL TIBIAL NAIL and T2 Femoral Nail. For this reason, when patients are recovering, the nail is strong enough to support them as the predicate devices do.

BIOCOMPATIBILITY

The system is made of TAV (Ti6Al4V), titanium alloy implant medical grade, which is considered as a biomaterial and is according to the ISO 5832- 03: Implants for surgery - Metallic materials - wrought titanium 6- aluminum 4-vanadium alloy.

There is no potential impact of the manufacturing processes when using titanium alloy Ti6Al4V on the biocompatibility of the final device according FDA submission K133166. It provides scientific information to demonstrate that the formulation change does not alter the chemical or physical properties of the medical device in its final finished form, and therefore, results from the Ins Hilden Tibial Arzzt PREDICATE DEVICE (**K133166**) can be applied to the medical devices in its final finished form.

There is no potential impact of the manufacturing processes when using titanium alloy Stainless Steel AISI 304 on the biocompatibility of the final device according FDA submission **K162507**. It provides scientific information to demonstrate that the formulation change does not alter the chemical or physical properties of the medical device in its final finished form, and therefore, results from the **ARZZT 3.5/4.5 Small and Large Fragment System** can be applied to the medical device in its final finished form, since both predicate and subject devices manufactured from the same material with the same manufacturing process with similar body contact and duration to each of the patient contacting instruments and the titanium screw.

DIFFERENCES

Design: Each design has slightly different geometry, with slight differences in angles, curvatures, and different lengths to fit the different long bones. These differences do not affect the final result, since each nail fits a specific bone, helping the stabilization and healing of the fracture.

REASONS WHY EACH DIFFERENCE DOES OR DOES NOT ADD NEW OR INCREASED RISKS AND COMPLICATIONS

Design

The design differences do not increase risks and complications. Since the systems designed to fit specific bones, so as the predicate devices are designed to fit a specific bone. The performance of all, is according.

POTENTIAL BENEFITS

Each system is designed to fit the specific type of bone.

FINAL CONCLUSION

Based on the technological properties of the subject devices as compared to the predicate devices, we understand that no new questions of safety and effectiveness have been raised, and that the subject devices are substantially equivalent to the predicate devices.