DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NORMED Medizin-Tecknik GmbH
Mr. Arne Briest
Regulatory Affairs Manager
Ulrichstrasse 7
D-78532 Tuttlingen
GERMANY

November 5, 2015

Re: K152256
Trade/Device Name: RECON system- Grubber Lapidus-, Platar Lapidus-, Tarsalis Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 7, 2015
Received: August 10, 2015

Dear Mr. Briest:

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 Parts 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,

Mark N. Melkerson -S

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)*
K152256

Device Name
RECON system - Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws

Indications for Use *(Describe)*
The implants are intended to support normal bone healing for osteotomies, fractures, and reconstructions.

The RECON system consists of various system components and it is indicated for the treatment of fracture fixation, joint decompression and fusion, reconstruction or arthrodeses of small bones. The system can be used in both adult and pediatric patients. Additional information is provided in the corresponding surgical techniques.

Gruber Lapidus
The Gruber Lapidus Plates 2.7 combined with the Standard/Locking/ MiniCAN screws 2.7 are indicated for TMT I joint arthrodesis with cuneiforme transfixation for correction of hallux valgus deformity.

Plantar Lapidus
The Plantar Lapidus Plates 2.7 combined with the Standard/Locking Screws 2.7 and the MiniCAN screws 3.5 are indicated for TMT I joint arthrodesis.

Tarsalis
The Tarsalis Plates 2.7 combined with the Standard/Locking Screws 2.7 are indicated for Lisfranc fusions and fracture fixation of the forefoot and midfoot.

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.

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510(k) Summary

1. Submission Sponsor and Correspondent

Normed Medizin-Technik GmbH
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Germany

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Contact: Mr. Arne Briest

FDA Establishment Registration #: 9611091

2. Date Prepared

Date Prepared: November 2, 2015

3. Device Identification

Trade/Proprietary Name:	RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws
Common/Usual Name:	bone plate and screw
Classification Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Regulation	21CFR 888.3030 21CFR 888.3040
Product Code:	HRS HWC
Device Class:	Class II
Classification Panel	Orthopedic

4. Legally Marketed Predicate Device

K010321 - Modular Foot System – 2.7 mm Module,
manufactured by Synthes Inc., cleared May 2, 2001

K063303 - Universal Locking Plate System 2.7, Plates and Screws,
manufactured by Zimmer Inc., cleared November 22, 2006

K060710 - Universal Locking Plate System 3.5, Plates and Screws
manufactured by Zimmer Inc., cleared April 26, 2006

K143066 - Zimmer Plates and Screws System (ZPS) – Non-sterile ZPS Plate Line Extensions, Sterile/Non-sterile ZPS Screws and Washers,
manufactured by Zimmer Inc., cleared November 28, 2014

K143165 - Herbert/Whipple Bone Screw System, Herbert Bone Screw, Herbert Cannulated Bone Screw System, and Herbert Mini Bone Screw,
manufactured by Zimmer Inc., cleared March 31, 2015

K151407 - Recon System,
manufactured by Normed Medizin-Technik GmbH, cleared August 12, 2015

K152142 - Recon System-MPJ-Plates,
manufactured by Normed Medizin-Technik GmbH, cleared September 16, 2015

5. Device Description

The RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws is a plate and screw system intended for internal fixation. The system consists of the following plates and screws:

- Gruber Lapidus Plates 2.7,
- Plantar Lapidus Plates 2.7,
- Tarsalis Plates 2.7,
- Locking Screws 2.7
- Standard Screws 2.7
- Minican Screws 2.7/3.5

of different sizes and designs.

The plates and screws are either made of titanium alloy Ti-6Al-4V (ASTM F136) or commercially pure Titanium (C.P. Titanium; ASTM F67).

The implants are offered in various sizes to accommodate the variations of bone size and geometry. The implants are provided non-sterile and single-use only. The instruments are non-sterile and reusable or for single use.

6. Indications for Use

The implants are intended to support normal bone healing for osteotomies, fractures, and reconstructions.

The RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws consists of various system components and it is indicated for the treatment of fracture fixation, joint decompression and fusion, reconstruction or arthrodeses of small bones. The system can be used in both adult and pediatric patients. Additional information is provided in the corresponding surgical techniques.

Gruber Lapidus
The Gruber Lapidus Plates 2.7 combined with the Standard/Locking/ MiniCAN screws 2.7 are indicated for TMT I joint arthrodesis with cuneiforme transfixation for correction of hallux valgus deformity.

Plantar Lapidus
The Plantar Lapidus Plates 2.7 combined with the Standard/Locking Screws 2.7 and the MiniCAN screws 3.5 are indicated for TMT I joint arthrodesis.

Tarsalis
The Tarsalis Plates 2.7 combined with the Standard/Locking Screws 2.7 are indicated for Lisfranc fusions and fracture fixation of the forefoot and midfoot.

7. Substantial Equivalence Discussion

The RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws have the same intended use, similar performance characteristics, is manufactured from similar materials and is similar in design to the predicate devices.

8. Non-Clinical Performance Data

- Biocompatibility – Biocompatibility testing on the plates was conducted and evaluated per ISO 10993-1. All testing passed.
- Cross sectional engineering analysis of the plates, proof load, bending strength, bending stiffness, equivalent bending stiffness and fatigue strength of the RECON System-Tarsalis Plates, the Lapidus Gruber Plates and the Plantar Lapidus Plates and the predicate devices, the Modular Foot System – 2.7 mm Module (K010321), Zimmer Universal Locking System (ULS) Plates and Screws (K063303 and K060710), and Zimmer Plates and Screws System (ZPS) (K143066) resulted in similar mechanical properties and performance. The subject and predicate devices are substantially equivalent.
- Bending strength engineering analysis for Minican Screws 2.7 mm and Minican Screws 3.5 mm (Partially-Treaded and Fully Threaded) and the predicate devices, the ZimmerBiomet Herbert Mini Bone screw (K143165) resulted in similar mechanical properties and performance. The subject and predicate devices are substantially equivalent.
- Self-tapping performance, driving and removal torque, torque to failure and axial pullout of the RECON System – Locking Screws 2.7mm, Standard Screws 2.7mm, MiniCAN Screws 2.7mm and MiniCAN Screws 3.5mm (Partial Thread) and the predicate devices, the Zimmer Universal Locking System (ULS) Plates and Screws (K063303 and K060710) and Herbert/Whipple Bone Screw System, Herbert Bone Screw, Herbert Cannulated Bone Screw System, and Herbert Mini Bone Screw (K143165), resulted in similar mechanical properties and performance. The subject and predicate devices are substantially equivalent.

9. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws and the predicate devices do not raise any questions regarding its safety and effectiveness.

Performance testing and compliance with voluntary standards, demonstrate that the RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

The RECON system – Gruber Lapidus-, Plantar Lapidus-, Tarsalis Plates and Screws are determined to be substantially equivalent to the referenced predicate devices.