 JUL 0 3 2014

510(k) Summary Pursuant to 21 CFR 807.92

General Company Information

Company Name:	Normed® Medizin-Tecknik GmbH
Company Address:	Ulrichstrasse 7 D-78532 Tuttlingen, Germany
Company Telephone:	+(011) 49 7461 93 43 0 +(011) 49 7461 93 43 20
Contact:	David Furr, MS FDC Services, LLC Principal Regulatory Affairs Consultant
Contact Address:	8708 Capehart Cove Austin, Texas 78733 (512) 906-9654
Date:	April 10, 2014
Device Trade Name:	*Normed* Vario Subtalar Screw
Common Name:	Subtalar Arthroereisis Implant
Classification Name:	Smooth & threaded metallic bone fixation fasteners (21 CFR 888.3040)
Class:	II
Product Code:	HWC
Predicate Device:	*Normed* Pellegrin Calcaneus Stop Screw, K133035 (cleared 12/13/13)

Memometal Technologies SubFix Arthroereisis Implant, K093820 (cleared 5/19/10)

Metasurg Subtalar Implant, K111265 (cleared 8/9/11)

Device Description:

The *Normed* Vario Subtalar Screw is a conical, threaded cannulated screw. It is designed to be inserted into the sinus tarsi of the foot for subtalar arthoroereisis. It is made from medical grade titanium alloy, Ti-6Al-4V (ASTM F136). The implant is offered in 2 sizes: Small (10mm – 13mm) and Large (13mm – 16mm). The implants are provided non-sterile and single-use only. The instruments are non-sterile and reusable.

Intended Use:

The Vario Subtalar Screw System is indicated for adult, children and adolescent patients.

The screws are intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Adult - additive subtalar alignment for flat foot.

Children - flexible flat foot treatment in children and adolescents.

Technological Characteristics:

The Vario Subtalar Screw System is similar to legally marketed predicate devices listed previously. The screws share

similar indications of use, are manufactured from the same materials and incorporate similar technological characteristics.

Performance Data (Nonclinical and/or Clinical):

Non-clinical testing demonstrated for the *Normed* Vario Subtalar Screw System meets performance requirements as defined by Design Control activities and are substantially equivalent to the predicate devices in terms of safety and efficacy. Summary of testing is as follows:

Testing	Standard
Vario Screws Static Compression Load	Custom Test
In-vitro cytotoxicity	ISO 10993-5
Sterility validation	Custom Test

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 Technik GmbH
% David Furr
Principal Regulatory Affairs Consultant
FDC Services,LLC
8708 Capehart Cove
Austin, Texas 78733

July 3, 2014

Re: K140962
Trade/Device Name: Normed Vario Subtalar Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 12, 2014
Received: May 14, 2014

Dear Mr. Furr:

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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140962

Device Name
Normed Vario Subtalar Screw

Indications for Use *(Describe)*

The Normed® Vario Subtalar Screw System is indicated for adult, children and adolescent patients.

The screws are intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Adult - additive subtalar alignment for flat foot.

Children - flexible flat foot treatment in children and adolescents.

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)*

Elizabeth D Frank -S

Division of Orthopedic Devices