



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

Normed Medizin-Technik GmbH
Mr. Arne Briest
RA/QA Manager
Ulrichstrasse 7
Tuttlingen, D-78532
Germany

January 26, 2016

Re: K151701

Trade/Device Name: Tenodesis screw system
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: December 23, 2015
Received: December 28, 2015

Dear Mr. Arne 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 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" (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.

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 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

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

Indications for Use

510(k) Number (if known)
K151701

Device Name
Tenodesis screw system

Indications for Use (Describe)

The Tenodesis screws are intended for soft tissue reattachment procedures in foot surgery.

The system is indicated for soft tissue reattachment procedures in foot surgery, such as tendon reconstructions and tendon transfers.

The system can be used in adult patients. Additional information is provided in the corresponding surgical techniques.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submission Sponsor and Correspondent

Normed Medizin-Technik GmbH
Ulrichstrasse 7
D-78532 Tuttlingen
Germany

Phone: + 49 7461 93 43 0
Fax: + 49 7461 93 43 20
Contact: Mr. Arne Briest

FDA Establishment Registration #: 9611091

2. Date Prepared

January 26, 2016

3. Device Identification

Trade/Proprietary Name:	Tenodesis screw system
Common/Usual Name:	Screw (smooth or threaded metallic bone fixation fastener)
Classification Name:	Screw, Fixation, Bone and Fastener, Fixation, Non degradable, Soft Tissue
Classification Regulation:	21CFR 888.3040
Product Code:	HWC/MBI
Device Class:	Class II
Classification Panel:	Orthopedic

4. Legally Marketed Predicate Device

K143165 - Herbert/Whipple Bone Screw System, Herbert Bone Screw, Herbert Cannulated Bone Screw System, and Herbert Mini Bone Screw

K061211 – NCB Cannulated Screw

K083150 - G-Force Tenodesis Screw

K051726 - Arthrex Tenodesis Screw Family

K041274 – Arthrex Resorbable Interference Screw (Rattler Interference Screw)

5. Device Description

The Tenodesis screw system is intended for soft tissue reattachment procedures in foot surgery. The screws are made of titanium alloy Ti-6Al-4V (ASTM F136). They are threaded, fully cannulated anchors.

The implants are offered in various sizes. The implants are provided non-sterile and single-use only.

The Tenodesis instruments are non-sterile and reusable.

6. Indications for Use

The Tenodesis screws are intended for soft tissue reattachment procedures in foot surgery.

The system is indicated for soft tissue reattachment procedures in foot surgery, such as tendon reconstructions and tendon transfers.

The system can be used in adult patients. Additional information is provided in the corresponding surgical techniques.

7. Substantial Equivalence Discussion

The Tenodesis screw system has the same intended use as the G-Force Tenodesis Screw, the Arthrex Tenodesis Screw Family and the Arthrex Resorbable Interference Screw. The Tenodesis screw system has similar performance characteristics, is manufactured from similar materials and is similar in design to the all selected predicate devices.

8. Non-Clinical Performance Data

- Biocompatibility – Biocompatibility testing on the plates was conducted and evaluated per ISO 10993-1. All testing passed.
- Self-tapping performance, driving, torsional properties and axial pullout strength of the Tenodesis screw system and the predicate devices 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 (G-Force Tenodesis Screw, Arthrex Tenodesis Screw Family and the Arthrex Resorbable Interference Screw) and the same technological characteristics (all selected predicates) 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 Tenodesis 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 Tenodesis screw system is 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 (G-Force Tenodesis Screw, Arthrex Tenodesis Screw Family and the Arthrex Resorbable Interference Screw).

The Tenodesis screw system is determined to be substantially equivalent to the referenced predicate devices.