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

April 3, 2017

Paragon 28
Karen E. Warden, Ph.D.
BackRoads Consulting Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K162241
Trade/Device Name: TITAN 3-D™ Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: PLF, HWC
Dated: February 18, 2017
Received: February 21, 2017

Dear Dr. Warden:

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,

Ronald P. Jean -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)*
K162241

Device Name
TITAN 3-D™ Wedge System

Indications for Use *(Describe)*

The TITAN 3-D™ Wedge System implants are intended to be used for internal bone fixation for bone fractures, fusions or osteotomies in the foot and ankle. The TITAN 3-D™ Wedge System implants are intended for use with ancillary fixation. The TITAN3-D™ Wedge System implants are not intended for use in the spine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Date:	8 August 2016
Sponsor:	Paragon 28 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Facsimile: (888) 728-1220
Sponsor Contact:	Frank S. Bono, Chief Technology Officer
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	TITAN 3-D™ Wedge System
Common Name:	Bone wedge
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Single/multiple component metallic bone fixation appliances and accessories, 888.3030, PLF Smooth or threaded metallic bone fixation fastener, 888.3040, HWC
Device Description:	The TITAN 3-D™ Wedge System contains a series of titanium alloy implants used for the correction of small bones in the foot. It is offered in varying shapes and sizes to accommodate a variety of small bone applications. The implants are sold sterile.
Indications for Use:	The TITAN 3-D™ Wedge System implants are intended to be used for internal bone fixation for bone fractures, fusions or osteotomies in the foot and ankle. The TITAN 3-D™ Wedge System implants are intended for use with ancillary fixation. The TITAN 3-D™ Wedge System implants are not intended for use in the spine.
Materials:	The TITAN 3-D™ Wedge System implants are manufactured from medical grade titanium alloy (per ASTM F2924).
Primary Predicate:	BIOFOAM® Bone Wedge (Wright Medical Technology, Inc. – K142724)
Additional Predicate:	4Web Osteotomy Bone Wedge (4Web Inc. – K130185)
Performance Data:	Static and dynamic compression, and static compression-shear testing was performed following ASTM F2077. Expulsion testing was performed. Abrasion testing per ASTM F1978 was performed. LAL testing for bacterial endotoxins was performed.
Technological Characteristics:	The TITAN 3-D™ Wedge System possesses the same technological characteristics as one or more of the predicate devices. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). Therefore the fundamental scientific technology of the TITAN 3-D™ Wedge System is similar to previously cleared devices.

Conclusion:	The TITAN 3-D™ Wedge System possesses indications for use and technological characteristics the same as the predicate devices. Therefore the TITAN 3-D™ Wedge System is substantially equivalent to the predicates.