March 5, 2018

Paragon 28
% Karen Warden
Representative/Consultant
BackRoads Consulting, Inc
PO Box 566
Chesterland, Ohio 44026-0566

Re: K171715
Trade/Device Name: HammerTube System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: January 22, 2018
Received: January 23, 2018

Dear Karen 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.

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

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 on last page.

510(k) Number *(if known)*

K171715

Device Name
HammerTube™ System

Indications for Use *(Describe)*

The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

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.

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"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

Date:	8 June 2017
Sponsor:	Paragon 28, Inc. 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 PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	HammerTube™ System
Common Name:	Fixation pin
Regulatory Class:	Class II
Classification Name / Regulation / Product Code:	Pin, Fixation, Smooth / 888.3040 / HTY
Device Description:	The HammerTube™ System includes HammerTube™ and K-wire implants. the HammerTube™ is a commercially pure titanium plasma sprayed PEEK cylinder in varying diameters and lengths. The K-wires are stainless steel and double trocar pointed.
Indications for Use:	The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures. The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint. The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System
Materials:	HammerTube™ System implants are manufactured from polyetheretherketone (VESTAKEEP, Evonik per ASTM F2026) having a commercially pure titanium plasma spray coating as described by ASTM F1580 or from stainless steel per ASTM F138.
Primary Predicate:	aap Wire Bone (aap Implante AG – K131459)
Reference Device:	Tyber Medical Wedge System (Tyber Medical LLC – K150394)
Performance Data:	Static and dynamic cantilever bending, and static pullout testing was performed.

Technological Characteristics:	The HammerTube™ System K-wire implants possesses the same technological characteristics as the predicate device. These include: • performance, • basic design, • material and • sizes (dimensions are comparable to those offered by the predicate systems). Differences between the HammerTube™ implants (material, design, sizes) were shown not to raise new questions of safety or effectiveness. Therefore the fundamental scientific technology of the HammerTube™ System is similar to the predicate.
Conclusion:	The HammerTube™ System possesses indications for use and technological characteristics similar to the predicate device. Therefore the HammerTube™ System is substantially equivalent to the predicate.