January 25, 2019

Paragon 28, Inc.
Eric Lintula
Director of Regulatory Affairs
4B Inverness Ct. E., STE 280
Englewood, Colorado 80112

Re: K183228
Trade/Device Name: HammerToe Compression System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: November 14, 2018
Received: November 20, 2018

Dear Mr. Lintula:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.01.25 11:03:16 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183228

Device Name
HammerToe Compression System

Indications for Use *(Describe)*
The HammerToe Compression System is indicated for use in the stabilization and inter-digital reconstruction of the phalanges of the foot, appropriate for the size of the device.

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 HammerToe Compression 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Paragon 28, Inc.

510(k) Summary

Date:	November 14th, 2018
Sponsor: **Sponsor contact:**	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Fax: (888) 728-1220 Eric Lintula, Director of Regulatory Affairs
Trade Name:	HammerToe Compression System
Regulatory Class:	Class II
Regulation, Product Code, Classification, and Common Name:	888.3040, HWC, Screw, Fixation, Bone 888.3040, HTY, Pin, Fixation, Smooth
Device Descriptions:	The HammerToe Compression System includes two intramedullary bone screws and a strut, which is provided pre-assembled with the proximal screw. Implantable K-wires are also provided in the system. The implants are provided in multiple diameters and lengths to accommodate variations in patient anatomy.
Indications for Use:	The HammerToe Compression System is indicated for use in the stabilization and inter-digital reconstruction of the phalanges of the foot, appropriate for the size of the device. 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 HammerToe Compression System.
Materials:	The HammerToe Compression System screws and strut are made from Titanium Alloy. The K-Wires are manufactured from Stainless Steel. The instrumentation is manufactured from medical grades of stainless steel, polymer and titanium.
Primary Predicate:	K171715, Paragon 28, Inc. HammerTube® System
Additional Predicate:	K130859, Arthrosurface, Inc. Hammertoe Correction System
Comparison to Predicate Indications:	The subject HammerToe Compression System and HammerTube® System devices are intended to be used for stabilization of small bones. All indications for the subject device are within the indications of the predicate devices.
Comparison to Predicate	Both the subject and the predicate components are designed to achieve stabilization of small bones. In the case of the HammerToe Compression System, the devices thread into the

Technological Characteristics:	medullary cavity of two adjacent small bones and engage with each other to provide tension and compress the two bones together. In the case of the predicate device and the implantable K-wires, the device passes through the medullary cavities of two adjacent small bones to provide stabilization for compressing the two bones together. Differences between the HammerToe Compression implants (material, design, sizes) were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the HammerToe Compression System is similar to the predicate.
Performance Data:	All necessary testing has been performed on representative HammerToe Compression System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices. The device performance was characterized via static and dynamic bending, pullout force, insertion/removal torque, and torque to failure testing. Clinical data are not needed to support the safety and effectiveness of the subject devices.
Conclusion:	Performance testing demonstrates the substantial equivalence of the HammerToe Compression System to the HammerTube® System. Therefore, the HammerToe Compression System is substantially equivalent to the HammerTube® System (K171715) with respect to their indications for use, technical characteristics, and function.