April 3, 2019

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

Re: K190586
Trade/Device Name: Monster® Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 5, 2019
Received: March 6, 2019

Dear Eric 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,

Shumaya Ali -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190586

Device Name
Monster® Screw System

Indications for Use *(Describe)*
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Fractures and Osteotomies
• Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
• Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
• Talar fractures
• Ankle fractures
• Navicular fractures
• Fractures of the fibula, malleolus, and calcaneus
• Metatarsal and phalangeal osteotomies
• Weil osteotomy
• Calcaneal osteotomy

Hallux Valgus Correction
• Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
• Interphalangeal (IP) arthrodesis
• Proximal, midshaft, or distal osteotomy
• Lapidus arthrodesis

Arthrodesis/Deformity Correction
• 1st MTP arthrodesis
• Metatarsal deformity correction
• Tarsometatarsal joint arthrodesis
• Naviculocuneiform joint arthrodesis
• Talonavicular arthrodesis
• Subtalar joint arthrodesis
• Triple arthrodesis
• Medial column arthrodesis
• Subtalar joint distraction arthrodesis
• Ankle arthrodesis
• Lateralizing calcaneal osteotomy
• Lateral column lengthening
• Hammertoe

Fusion resulting from neuropathic osteoarthropathy (Charcot) such as:
• Medial and lateral column
• Subtalar, talonavicular, and calcaneocuboid

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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"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."

5. 510(K) SUMMARY

Device Trade Name:	Monster® Screw System
510(k) Number:	K190586
Manufacturer:	Paragon 28, Inc. 4B Inverness Ct. E, Ste. 280 Englewood, CO 80112
Contact:	Mr. Eric Lintula Senior Director of Quality and Regulatory Affairs Phone: 888-728-1888 Email: elintula@paragon28.com
Prepared by:	Mr. Dave McGurl Director, Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NE, Suite 1000 Washington, DC 20005 Phone: 202.552.5800 dmcgurl@mcra.com
Date Prepared:	March 5, 2019
Classification:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
Class:	II
Product Code:	HWC; Screw, fixation, bone
Primary Predicate Device:	Paragon 28 Monster Screw System (K124027, K151418, K153378)
Additional Predicates:	Wright MICA Screw (K162353) Extremity Medical Axis Charcot Fixation System (K171018) Biomet Headless Compression and Twist-Off Screws (K142658) Extremity Medical Screw and Washer System (K101700) Acumed Cannulated Screw System (K123890)

Indications for Use:
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Paragon 28 Monster Screw System – Special 510(k)

Fractures and Osteotomies
- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
- Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
- Talar fractures
- Ankle fractures
- Navicular fractures
- Fractures of the fibula, malleolus, and calcaneus
- Metatarsal and phalangeal osteotomies
- Weil osteotomy
- Calcaneal osteotomy

Hallux Valgus Correction
- Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Arthrodesis/Deformity Correction
- 1st MTP arthrodesis
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- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Fusion resulting from neuropathic osteoarthropathy (Charcot) such as:
- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

Device Description:
The Monster Screw System is comprised of threaded bone screws (Ti Alloy or Stainless Steel) offered in 2.0mm to 9.5mm diameters (in 0.5mm increments). In addition, a 2.7mm diameter is also part of the system. The overall screw length ranges from 8mm (for smaller diameters) thru 200mm (for larger diameters). The screws are available in a variety of designs including: fully or partially threaded, self-drilling or blunt, cannulated or solid, and headed or headless. Sized-matched washers are also available.

Paragon 28 Monster Screw System – Special 510(k)

Substantial Equivalence of Indications for Use:
With respect to the primary predicate, the proposed Monster Screw System has the same indications. Specifically, both systems are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. The difference between the two systems is that the subject device lists specific examples of the indications. These specific examples are encapsulated in the indications of the primary predicate, and specifically identified in the indications of the additional predicates.

Substantial Equivalence of Technological Characteristics:
The subject Monster Screw System components possess the same technological characteristics as the predicate devices. These include:

- performance,
- basic design,
- material, manufacturing and
- sizes (dimensions are comparable to those offered by the predicate systems).

Differences between the Monster Screw System implants and the predicate devices (i.e. modified head, thread and tip features, and additional components) were shown not to raise new questions of safety and effectiveness. Therefore, the Monster Screw System is substantially equivalent to the predicate devices with respect to indications, design, function, and performance.

Preclinical Testing:
Engineering analysis is presented to provide evidence that the original testing and subsequent performance is not adversely affected by the modifications to the subject devices. In addition, torsional, pullout, and insertion/removal evaluations were conducted for the modified components. Sterilization validations were also performed for the additional components. The results of the preclinical testing demonstrated the subject designs are substantially equivalent to the predicate devices.

Clinical Testing:
Clinical testing was not necessary to support equivalence.

Conclusion:
The Monster Screw System possesses the same intended use and technological characteristics as the predicate devices. Therefore, the Monster Screw System is substantially equivalent for its intended use.