November 13, 2020

Paragon 28, Inc.
Haylie Hertz
Regulatory Affairs Specialist
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K203011
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: September 29, 2020
Received: October 1, 2020

Dear Haylie Hertz:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K203011

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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510(k) Summary

510(k) Number: K203011

Device Trade Name: Monster Screw System

Manufacturer: Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112

Contact: Haylie Hertz
Phone: 303-720-0017
hhertz@paragon28.com

Date Prepared: November 13, 2020

Common Name: Bone Screw

Classification: 21 CFR 888.3040, smooth or threaded bone fixation fastener

Class: II

Product Code: HWC

Predicate Device: Monster Screw System (K190586)

Reference Devices: Hammertoe Compression System (K183228)
JAWS Nitinol Staple System (K170923)

Indications for Use:
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fraction, 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
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Arthrodesis/Deformity Correction
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- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint 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 results from neuropathic osteoarthropathy (Charcot) such as:
- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

Device Description:
The Monster Screw System contains bone screws of various diameters, lengths, and configurations. One configuration is a snap-off style bone screw offered in two diameters having various overall and threaded lengths.

Substantial Equivalence:
The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. In addition, the subject device possesses the same technological characteristics as the predicate device, including performance, basic design, material, manufacturing, and sizes. Differences between the Monster screws and the predicate device were shown not to raise new questions of safety and effectiveness. Therefore, the Monster Screw System is substantially equivalent to the predicate device cited on the previous page with respect to indications, design, function, and performance.

Non-clinical Testing:
Non-clinical testing used to support equivalence included: sterilization validation (ISO 11137-1), cleaning validation (ASTM F2459), cytotoxicity (ISO 10993-5), bacterial endotoxins (ANSI/AAMI ST72), distribution validation (ASTM D4169) assessed via visual inspection (ASTM F1886), seal strength (ASTM F88), and bubble leak evaluations (ASTM F2096), and shelf-life validation assessed via visual inspection (ASTM F1886), seal strength (ASTM F88), and dye leak evaluations (ASTM F1929).

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 device. Therefore, the Monster Screw System is substantially equivalent for its intended use.