DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 21, 2015

Paragon 28, Incorporated
% Karen E. Warden, Ph.D.
Representative/Consultant
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026-0566

Re: K153378
Trade/Device Name: Monster BITE 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: November 20, 2015
Received: November 23, 2015

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 yours,

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)*

K153378

Device Name

Monster BITE Screw System™

Indications for Use *(Describe)*

The Monster BITE 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

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)*

510(k) Summary

Date:	20 November 2015
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:	Monster BITE Screw System™
Device Classification	Class II
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation:	888.3040
Device Product Code:	HWC
Submission Purpose:	This submission addresses modified dimensions of the cleared Monster Screw components and adds the Monster BITE Screw System to the Monster Screw System™ family.
Device Description:	The Monster BITE Screw System™ includes snap-off, threaded bone screws offered in 2.0mm and 2.7mm diameters having overall lengths from 8 to 24mm.
Intended Use:	The Monster BITE 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.
Materials:	The Monster BITE Screw System™ implants are manufactured from medical grade titanium alloy (per ASTM F136).
Predicate Devices:	Primary: Paragon 28 (K151418)
Reference Devices:	Paragon 28 (K124027) Smith & Nephew (K090675) OsteoMed Corp. (K924018)
Performance Data:	Theoretical comparisons of torsion and pullout strength along with insertion/removal torque testing per ASTM F543 demonstrated the Monster BITE Screw System™ mechanical performance to be substantially equivalent to the predicate devices.
Technological Characteristics:	The Monster BITE Screw System™ possesses the same technological characteristics as one or more of the predicate devices. These include: • performance (as described above), • basic design (threaded fastener), • material (titanium alloy) and • sizes (dimensions are comparable to those offered by the predicate systems). Therefore the fundamental scientific technology of the Monster BITE Screw System™ is the same as previously cleared devices.

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