



Food and Drug Administration  
10903 New Hampshire Avenue  
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July 15, 2015

Paragon 28  
% Karen Warden, Ph.D.  
Backroads Consulting, Inc  
P.O. Box 566  
Chesterland, Ohio 44026-0566

Re: K151418  
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, HTN  
Dated: June 16, 2015  
Received: June 17, 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 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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement on last page.

### Indications for Use

510(k) Number (if known)

K151418

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

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)

## **Section 8 – 510(k) Summary**

<b>Date:</b>	26 May 2015
<b>Sponsor:</b>	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Facsimile: (888) 728-1220
<b>Sponsor Contact:</b>	Frank S. Bono, Chief Technology Officer
<b>510(k) Contact:</b>	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
<b>Trade Names:</b>	Monster Screw System™
<b>Device Classification</b>	Class II
<b>Classification Name:</b>	Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories
<b>Regulation:</b>	888.3040, 888.3030
<b>Device Product Code:</b>	HWC, HTN
<b>Submission Purpose:</b>	This submission addresses modified dimensions of the cleared 2.0 Monster Screw components.
<b>Device Description:</b>	The Monster Screw System™ is comprised of bone screws and washers. The Monster Screw is a threaded bone screw offered in 2.0mm to 9.5mm diameters (in 0.5 mm increments) having overall lengths from 8mm (for smaller diameters) thru 200mm (for larger diameters). The screws are offered having a variety of features with respect to head, thread, tip, cannulation and material. Size-matched washers are also available.
<b>Intended Use:</b>	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.
<b>Materials:</b>	The Monster Screw System™ implants are manufactured from medical grade titanium alloy (per ASTM F136) and stainless steel alloy (per ASTM F2229).
<b>Predicate Devices:</b>	Primary: Paragon 28 (K124027) Reference: Vilex Inc (K973309, K991151, K991197 and K014154) OsteoMed Corp. (K924018)
<b>Performance Data:</b>	Theoretical comparisons demonstrated the Monster Screw System™ mechanical performance to be substantially equivalent to the predicate devices.

**Technological  
Characteristics:**

The Monster 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 and/or stainless steel alloys) and
- sizes (dimensions are comparable to those offered by the predicate systems).

Therefore the fundamental scientific technology of the Monster Screw System™ is the same as previously cleared devices.

**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.