



Food and Drug Administration
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Silver Spring, MD 20993-0002

Paragon 28
% Karen Warden
Representative/Consultant
BackRoads Consulting, Inc
PO Box 566
Chesterland, Ohio 44026-0566

July 24, 2017

Re: K170923
Trade/Device Name: JAWS™ Nitinol Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And
Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: June 8, 2017
Received: June 9, 2017

Dear Karen 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170923

Device Name

JAWS™ Nitinol Staple System

Indications for Use (Describe)

The JAWS™ Nitinol Staple System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of bones and joint of the foot including fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.”

510(k) Summary

Date:	27 March 2017
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, Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	JAWS™ Nitinol Staple System
Common Name:	Bone staple
Regulatory Class:	Class II
Classification Name / Regulation / Product Code:	Staple, fixation, bone / 888.3030 / JDR
Device Description:	The JAWS™ Nitinol Staple System includes three styles of bone staples having various sizes to accommodate a variety of small bone applications. The implants and instruments are sold sterile.
Indications for Use:	The JAWS™ Nitinol Staple System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of bones and joint of the foot including fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.
Materials:	The JAWS™ Nitinol Staple System implants are made from Nitinol (ASTM F2063).
Primary Predicate:	OSStaple (BioMedical Enterprises, Inc. – K001354)
Additional Predicates:	Biopro Memory Staple (Biopro, Inc. – K061798), Memodyn Staple (Telos Medical Equipment – K002695), Super Staple™ Classic (Metric Medical Devices, Inc. – K123363)
Performance Data:	Static and dynamic bending, and pullout fixation strength testing was performed according to ASTM F564. In addition, corrosion testing per ASTM F2129 was performed.
Technological Characteristics:	The JAWS™ Nitinol Staple System possesses the same technological characteristics as one or more of the predicate devices. These include: <ul style="list-style-type: none"> • performance, • basic design, • material and • sizes (dimensions are comparable to those offered by the predicate systems). <p>Therefore the fundamental scientific technology of the JAWS™ Nitinol Staple System is similar to previously cleared devices.</p>

Conclusion:

The JAWS™ Nitinol Staple System possesses indications for use and technological characteristics the same as the predicate devices. Therefore the JAWS™ Nitinol Staple System is substantially equivalent to the predicates.