May 11, 2023

Paragon 28 Inc
Haylie Hertz
Senior Regulatory Affairs Specialist
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K230550
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: March 15, 2023
Received: March 15, 2023

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230550

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 the bones and joints 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY

510(k) Number:	K230550
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Hertz Associate Regulatory Affairs Specialist Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 303-720-0017 hhertz@paragon28.com
Date Prepared:	May 11, 2023
Device Trade Name:	JAWS® Nitinol Staple System
Device Class and Common Name:	Class II, staple, fixation, bone
Classification:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Product Codes:	JDR
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.
Device Description:	The JAWS® Nitinol Staple System are bone staples of various sizes to accommodate a variety of small bone applications. The implants and instruments are sold sterile.
Predicate Device:	JAWS® Nitinol Staple System (K223056)

Substantial Equivalence:	The proposed JAWS® Nitinol Staple System is substantially equivalent to the predicate JAWS® Nitinol Staple System (K223056) with respect to indications, design, material and function.
Performance 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. Testing on MR compatibility and corrosion was also conducted. The results of this analysis and testing demonstrated the modified designs are substantially equivalent to the predicate devices.
Conclusions:	The JAWS® Nitinol Staple System subject to this submission possesses the same intended use and technological characteristics as the predicate device system components. All performance testing conducted for the JAWS® Nitinol Staple System met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the JAWS® Nitinol Staple System components are substantially equivalent to the predicate devices for the intended use.