February 16, 2023

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

Re: K223056
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: January 20, 2023
Received: January 20, 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)*
K223056

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: K223056

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

Contact: Haylie Hertz
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Paragon 28, Inc.
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Englewood, CO 80112
Phone: 303-720-0017
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Date Prepared: January 20, 2023

Device Trade Name: JAWS Nitinol Staple System

Device Class: Class II

Predicate Device: JAWS Nitinol Staple System (K170923)

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.

Classification and Product Code: 21 CFR 888.3030; Staple, fixation, bone, 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.

Substantial Equivalence: The intended use, principle of operation and fundamental scientific technology of the modified device are identical to the predicate device. The MR safety and compatibility performance and labeling modifications were accomplished via testing in the MRI environment and updated labeling per the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021. The data

demonstrate substantial equivalence and the subject modifications do not raise new issues of safety or effectiveness.

Performance Testing:

MR Safety and Compatibility Testing has been completed and presented in the submission as recommended in the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021, including FDA-recognized standards tests for the following potential hazards:

- Image Artifact per ASTM F2119 *Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- Magnetically Induced Displacement Force per ASTM F2052 *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- Magnetically Induced Torque per ASTM F2213 *Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- Radiofrequency (RF) Induced Heating per ASTM F2182 *Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging*
- Computational Modeling and Simulation of Radiofrequency Induced Heating in the Magnetic Resonance Environment

Based on the results, the JAWS Nitinol Staples will be labeled as "MR Conditional" with MRI Safety Information in the instructions for use as described in ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*

Conclusion:

The proposed device modifications do not raise new issues of safety or effectiveness and has been fully evaluated. The subject devices are substantially equivalent to the legally marketed, predicate device.