January 14, 2021

Paragon 28, Inc.
% Dave McGurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K202019
Trade/Device Name: Paragon 28 MAVEN™ Patient-Specific Instrumentation
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN, OYK
Dated: December 8, 2020
Received: December 9, 2020

Dear Dave McGurl:

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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202019

Device Name
Paragon 28 MAVEN™ Patient-Specific Instrumentation

Indications for Use *(Describe)*
The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended for use with the Paragon 28 APEX 3D Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended for single use only. The Paragon 28 TAR Patient-Specific Case Reports are intended for use with the Paragon 28 APEX 3D Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

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.

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510(k) Summary

Manufacturer: Paragon 28, Inc.
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Washington, DC 20001
Phone: 202.552.5800

Date Prepared: January 14, 2021

510(k) Number: K202019

Device Trade Name: Paragon 28 MAVEN™ Patient-Specific Instrumentation

Device Common Name: Total Ankle Prosthesis

Classification: 21 CFR 888.3110
Class II

Product Code: HSN, OYK

Indications for Use:
The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended for use with the Paragon 28 APEX 3D Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The Paragon 28 MAVEN™ Patient-Specific Instrumentation is intended for single use only. The Paragon 28 TAR Patient-Specific Case Reports are intended for use with the Paragon 28 APEX 3D Total Ankle Replacement System and its cleared indications for use, provided that

anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

Device Description:
The Paragon 28 MAVEN™ Patient-Specific Instrumentation is used in conjunction with the APEX 3D Total Ankle Replacement System instrumentation (K192994). The guides are created to fit the anatomy of the patient's distal tibia and proximal talus, and when used in combination with the APEX 3D instruments, facilitate positioning of the APEX 3D implants.

Predicate Devices:
The Paragon 28 MAVEN™ Patient-Specific Instrumentation is substantially equivalent to the PROPEHCY INFINITY Pre-Operative Navigation System (K170968). The APEX 3D Total Ankle Replacement System (K192994) is an additional predicate device and VSP Orthopedics System (K190044) is considered a reference device.

Technological Characteristics:
The subject Paragon 28 MAVEN Patient-Specific Instrumentation components possess the same technological characteristics as the predicate devices. These include:

- performance,
- basic design,
- material, manufacturing and
- sizes (dimensions are comparable to those offered by the predicate systems).

Differences between the MAVEN Patient-Specific Instrumentation and the predicate devices were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the subject Paragon 28 MAVEN Patient-Specific Instrumentation is similar to previously cleared devices.

Performance Data:
All necessary testing has been performed on representative Paratrooper™ Plantar Plate Repair System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices.
The device performance was characterized via Guide Design Process Validation, Pre-operative vs Post-Operative Analysis of Implant Placement and Resection Location, and Software Validation. Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusion:
Performance testing demonstrates the substantial equivalence of the Paragon 28 MAVEN Patient-Specific Instrumentation to the Wright Medical PROPEHCY INFINITY Pre-Operative Navigation System. Therefore, the MAVEN PSI System is substantially equivalent to the predicate devices with respect to their indications for use, technical characteristics, and function.