November 17, 2022

Paragon 28, Inc.
% Jan Triani
Regulatory Affairs Consultant
Triani Consulting, LLC
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K223227
Trade/Device Name: 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: October 17, 2022
Received: October 18, 2022

Dear Jan Triani:

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 -S

Ting Song, 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)*
K223227

Device Name
MAVEN™ Patient Specific Instrumentation

Indications for Use *(Describe)*

The MAVEN™ Patient-Specific Instrumentation System 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 MAVEN™ Patient- Specific Instrumentation System 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 MAVEN™ Patient-Specific Instrumentation System 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.

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

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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

Paragon 28, Inc. MAVEN Patient Specific Instrumentation

Manufacturer: Paragon 28, Inc
14445 Grasslands, Dr.
Englewood, CO 80112
Phone: 855-786-2525

Official Contact: Jan Triani
Regulatory Consultant
Patient Specific, Paragon 28, Inc.

Date Prepared: October 11 ,2022

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

Device Common Name: Patient Specific Guide

Classification: 21 CFR 888.3110

Product Code: HSN, OYK

Purpose of the Special 510(k) notice:

The modification to the subject device is to allow an additional material and supplier to make the subject device.

Intended Use

The intended use and indication are the same as the main predicate device, K202019. Indications are:

> The MAVEN™ Patient-Specific Instrumentation System 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 MAVEN™ Patient- Specific Instrumentation System 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 MAVEN™ Patient-Specific Instrumentation System 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 (PSI) system is intended to assist a surgeon with pre-operative planning and transfer of the pre-operative plan to the surgery in total

ankle replacement procedures. The system contains several physical and digital outputs including patient-specific anatomical models and guides (physical outputs); and a patient-specific case report (digital or documentation output).

The MAVEN™ PSI System is for use with the APEX 3D™ Total Ankle Replacement System.

Performance Data

The company conducted a design and manufacturing process validation, to demonstrate that the changes presented within this premarket submission, did not change the outputs, which is the creation of a patient specific instrument. The validation successfully demonstrated the minor changes made to the subject device are substantially equivalent to the predicate.

Substantial Equivalence

The modification made to the MAVEN Patient Specific Instrumentation are minor. The subject device has the same intended use and same indications, and principles of operation, as the primary predicate (K202019). The minor differences in the grade of nylon and OTS design software do not raise any new questions of safety or effectiveness. The subject device is made by the same supplier, from the same nylon material and manufacturing methods, and uses the same software as the secondary predicate (K211076). Performance data demonstrates that the subject device is as safe and effective as the predicate devices. Thus, the subject device is substantially equivalent to its predicate devices.

Conclusions

In summary, the company's modified MAVEN Patient Specific Instrumentation has the same intended use as all of the previously cleared MAVEN Patient Specific Instrumentation (K202019). In addition, the modified device has the same indications, technological characteristics, and principles of operation as its primary predicate. Although there are minor differences between the subject and its primary predicate device, namely the grade of nylon material and the OTS software used by the design engineers, those differences do not raise new questions of safety or efficacy, and data provided in this and previous 510(k)s establish equivalence. Thus, the subject device is substantially equivalent.