March 6, 2021

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

Re: K210390
Trade/Device Name: Apex 3D Total Ankle Replacement System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: February 5, 2021
Received: February 9, 2021

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,

For 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)*

K210390

Device Name
APEX 3D Total Ankle Replacement System

Indications for Use *(Describe)*
The APEX 3D Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. Components are intended for cemented use only.

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

510(k) Number: K210390

Device Trade Name: APEX 3D Total Ankle Replacement System

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

Contact: Ms. Haylie Hertz
Regulatory Affairs Specialist
Phone: 303.720.0017
hhertz@paragon28.com

Date Prepared: March 1, 2021

Classification: 21 CFR §888.3110; Ankle joint metal/polymer semi-constrained cemented prosthesis

Class: II

Product Code: HSN

Common Name: Total Ankle Replacement

Predicate Device: APEX 3D Total Ankle Replacement System (K192994)

Reference Device: Agility Ankle Revision Prosthesis (K020541)

Indications for Use:
The APEX 3D Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. Components are intended for cemented use only.

Device Description:
The Paragon 28 APEX 3D Total Ankle Replacement device is a cemented, fixed-bearing device comprised of a tibial component, a talar component, and a UHMWPE component used for ankle joint replacement. Based on patient anatomy, a number of component sizes and design configurations can be selected for best fit.

Substantial Equivalence:
The subject APEX 3D Total Ankle Replacement System and the predicate system are intended to be used in total ankle arthroplasty procedures. The indications for the subject device are identical to the indications of the predicate device.

The subject APEX 3D Total Ankle Replacement components possess the same technological characteristics as the predicate device. These include:

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

Differences between the APEX 3D Total Ankle Replacement implants and the predicate devices (TPS coating) were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the subject APEX 3D Total Ankle Replacement System components is similar to previously cleared device.

Performance Data:
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. This included a talar stability assessment and bacterial endotoxin testing.
The results of the analysis demonstrated the modified designs are substantially equivalent to the predicate device.

Conclusion:
The modified APEX 3D Total Ankle Replacement System possesses the same indications for use and technological characteristics as the predicate APEX 3D Total Ankle Replacement System (K192994). Therefore, the APEX 3D Total Ankle Replacement System is substantially equivalent to the predicate device with respect to indications for use, technical characteristics, and function