July 10, 2020

Paragon 28, Inc.
% Hollace Rhodes
Vice President, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K192994
Trade/Device Name: Paragon 28 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: June 19, 2020
Received: June 19, 2020

Dear Hollace Rhodes:

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.
Acting 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)*

K192994

Device Name
Paragon 28 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.

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

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510(k) Summary

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

Contact: Mr. Eric Lintula
Senior Director of Quality and Regulatory Affairs
Phone: 855-786-2828
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Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: November 20, 2019

Device Trade Name: Paragon 28 APEX 3D Total Ankle Replacement System

Device Common Name: Total Ankle Prosthesis

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

Class II

Product Code: HSN

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.

Performance Testing Summary:
Performance data for the Paragon 28 APEX 3D Total Ankle Replacement System demonstrate its substantial equivalence to the INVISION Total Ankle Revision System (K171067), Salto XT, Salto Talaris (K153452) and the Integra Cadence Total Ankle System (K151459). Testing performed on the subject devices includes:

- Range of Motion
- Contact Stress and Contact Area
- Constraint
- Disassembly Strength of the Tibial Tray and Insert
- Cantilever Fatigue Strength of Tibial Tray
- Polyethylene Wear
- Porous Structure Characterization
- Pyrogenicity (LAL) Testing

Each of these studies were designed to address risks and demonstrate substantially equivalent performance to predicate devices.

Predicate Devices:
The Paragon 28 APEX 3D Total Ankle Replacement System is substantially equivalent to the INVISION Total Ankle Revision System (K171067), Salto XT, Salto Talaris (K153452) and the Integra Cadence Total Ankle System (K151459).

Substantial Equivalence:
The subject system is substantially equivalent to the predicate systems with respect to intended use, indications, design, materials and available size range. Non-clinical testing performed included range of motion, contact stress and contact area analysis, constraint characteristic testing, disassembly testing, polyethylene wear testing, fatigue cantilever testing, material characterization, and user validation. The results of this testing demonstrate that the subject system performs as intended with results exceeding anticipated physiologic loads. Additionally, the Paragon 28 APEX 3D Total Ankle Replacement System is in compliance with LAL testing requirements for orthopedic implants.

Conclusion:
The nonclinical testing demonstrates that the Paragon 28 APEX 3D Total Ankle Replacement System is as safe, as effective, and perform as well as or better than the predicate devices.