June 24, 2024

Paragon 28, Inc.
Haylie Fast
Associate Manager of Regulatory Affairs
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K240259
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 16, 2024
Received: February 16, 2024

Dear Haylie Fast:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240259

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. In the United States, 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.

510(K) SUMMARY

510(k) Number:	K240259
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Fast Manager of Regulatory Affairs Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 720-994-5489 hfast@paragon28.com
Date Prepared:	June 21st, 2024
Device Trade Name:	APEX 3D Total Ankle Replacement System
Device Class and Common Name:	Class II, Total Ankle Prosthesis
Classification:	21 CFR 888.3110: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
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. In the United States, components are intended for cemented use only.
Device Description:	The APEX 3D Total Ankle Replacement System 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.

Primary Predicate: Paragon 28 APEX 3D Total Ankle Replacement System (K192994)

Reference Device: INBONE Total Ankle System (K193067)

Substantial Equivalence: The APEX 3D Total Ankle Replacement System is substantially equivalent to the legally marketed predicate device systems with respect to intended use and design. The subject Short Stem Tibia implant is identical to the cleared APEX 3D Tibial Trays in terms of material, shape, and dimensions of the tray. The way the implants differ is the anterior fixation feature. The subject device proposes a central stem, the predicate device has two pegs. The MR Conditional labeling is also updated.

The differences in technological characteristics between the subject device and predicate device were shown not to introduce different questions of safety and effectiveness.

Performance Testing: All necessary testing has been performed on representative APEX 3D Total Ankle Replacement components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices. Non-clinical testing included:

- Cantilever Fatigue
- Porous Structure Characterization
- Porous Structure Tensile, Static Shear, Fatigue Shear, Abrasion
- Tibial Stem Stability (Micromotion)
- Shear Strength of Stem
- Residual Powder
- 3D Printing Process Validation
- Image Artifact
- Magnetically Induced Displacement Force
- Magnetically Induced Torque
- Radiofrequency (RF) Induced Heating

Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusions: The APEX 3D Total Ankle Replacement System subject to this submission possesses the same intended use and has similar technological characteristics as the predicate device system components. The performance testing demonstrates that the APEX 3D Total Ankle Replacement System is as safe and effective as the predicate device.