May 1, 2025

Paragon 28, Inc.
Edward Wells-Spicer
Regulatory Affairs Specialist II
14445 Grasslands Dr
Englewood, Colorado 80112

Re: K250641
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: March 3, 2025
Received: March 4, 2025

Dear Edward Wells-Spicer:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250641

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.

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

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510(K) SUMMARY

510(k):	K250641
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Edward Wells-Spicer Regulatory Affairs Specialist II Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 720-994-5481 ewspicer@paragon28.com
Date Prepared:	April 30, 2025
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 has been cleared under K192994. The purpose of this submission is to introduce a new diffusion bonded talar dome to the APEX 3D

	Total Ankle Replacement System. 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:	APEX 3D Total Ankle Replacement System (K192994)
Additional Predicate Device:	Zimmer Trabecular Metal Total Ankle (K120906)
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 device and the primary predicate have identical indications for use. The differences between the technological characteristics of the subject device and primary predicate are manufacturing methods, but the raw materials contained in the subject talar dome component are identical to materials in components of the primary predicate. The diffusion bonding manufacturing method of the subject device is the same method as the manufacturing method for the additional predicate device. 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 or representative devices. Clinical data are not needed to support the safety and effectiveness of the subject device. List of nonclinical tests provided in this submission: • Porous Structure Characterization • Diffusion Bonded Tensile Strength • Diffusion Bonded Static Shear Strength • Diffusion Bonded Fatigue Shear Strength • Diffusion Bonded Abrasion Resistance • Metallurgical Analysis • Accelerated Corrosion Soak

Conclusions: APEX 3D Total Ankle Replacement subject to this submission possesses the same intended use and has similar technological characteristics as the predicate device system components. All performance testing conducted for the APEX 3D Total Ankle Replacement met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the APEX 3D Total Ankle Replacement system components are substantially equivalent to the predicate devices.