August 22, 2023

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

Re: K231496
Trade/Device Name: TITAN 3-D Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF
Dated: May 23, 2023
Received: May 24, 2023

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,

Shumaya Ali -S

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*

K231496

Device Name
TITAN 3-D® Wedge System

Indications for Use *(Describe)*

The TITAN 3-D® Wedge System implants are indicated to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the foot and ankle. The TITAN 3-D® Wedge System implants are intended for use with ancillary fixation. The TITAN 3-D® Wedge System implants are not indicated for use in the spine.

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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K231496

510(K) SUMMARY

510(k) Number: K231496

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

Contact: Haylie Hertz
Associate Manager of Regulatory Affairs
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
Phone: 303-720-0017
hhertz@paragon28.com

Date Prepared: August 22, 2023

Device Trade Name: TITAN 3-D® Wedge System

Device Class: Class II

Predicate Device: TITAN 3-D® Wedge System (K162241)

Device Description: The TITAN 3-D® Wedge System contains a series of titanium alloy implants used for the correction of small bones in the foot. It is offered in varying shapes and sizes to accommodate a variety of small bone applications. The implants are sold sterile.

Classification and Product Code: 21 CFR 888.3030; Single/multiple component metallic bone fixation appliances and accessories; PLF

Indications for Use: The TITAN 3-D® Wedge System implants are indicated to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the foot and ankle. The TITAN 3-D® Wedge System implants are intended for use with ancillary fixation. The TITAN 3-D® Wedge System implants are not indicated for use in the spine.

Substantial Equivalence: The intended use, principle of operation and fundamental scientific technology of the modified device are identical to the predicate device. The MR safety and compatibility performance was assessed via testing in the MRI environment and labeling was updated per the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021. The data demonstrate substantial equivalence and the subject modifications do not raise new issues of safety or effectiveness.

The subject device has the addition of new contract suppliers and repeated performance testing has indicated that the supplier change does not raise new issues of safety or effectiveness. There are no

new chemicals or processes that the implant is exposed to when compared to the predicate therefore no new issues of safety and effectiveness are raised.

Performance Testing:

MR Safety and Compatibility Testing has been completed and presented in the submission as recommended in the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021, including FDA-recognized standards tests for the following potential hazards:

- Image Artifact per ASTM F2119 *Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- Magnetically Induced Displacement Force per ASTM F2052 *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- Magnetically Induced Torque per ASTM F2213 *Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- Radiofrequency (RF) Induced Heating per ASTM F2182 *Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging*

Based on the results, the TITAN 3-D® Wedge System will be labeled as "MR Conditional" with MRI Safety Information in the instructions for use as described in ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*

Performance testing for dynamic compression, static compression, and static compressive shear verified the change does not raise new questions of safety and effectiveness.

Conclusion:

The proposed device modifications do not raise new issues of safety or effectiveness and have been fully evaluated. The subject devices are substantially equivalent to the legally marketed predicate device.