June 28, 2022

Additive Orthopaedics, LLC
% Jan Triani
Director QA/RA
Paragon 28, Inc.
44 Riverdale Ave
Monmouth Beach, New Jersey 07750

Re: K211076
Trade/Device Name: Patient Specific Marking Guides
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: April 8, 2021
Received: April 12, 2021

Dear Jan Triani:

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: Shumaya Ali, M.P.H.
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)*
K211076

Device Name
Patient Specific Marking Guide

Indications for Use *(Describe)*
The Paragon 28 Patient Specific Marking Guide is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies for adult patients in the foot and ankle. The Patient Specific Guide is not intended to directly guide the cutting of bone. The device is single 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510K Summary - K211076

1. INRODUCTION

This document contains the 510(k) summary for the Paragon 28, Inc. Patient Specific Marking Guides. The content of this summary is based on Per 21 CFR 807.92

2. SUBMITTER

Name:	Paragon 28, Inc.
Address:	44 Riverdale Ave Monmouth Beach, NJ 07750 Phone: (855)786-2828
Official Contact	Jan Triani Regulatory Consultant Patient Specific Paragon 28, Inc.
Date Prepared:	May 31, 2022

3. DEVICE INFORMATION:

Trade Name:	Patient Specific Marking Guides
Common Name:	Patient specific orthopedic anatomical models, templates, and guides
Classification Name:	Orthopaedic Surgical Planning and Instrument Guides
Classification:	21 CFR 888.3030
Product Code:	PBF

4. PREDICATE DEVICES

Predicate Device:

- VSP® Orthopedics System, 3D Systems, Inc. (K190044)

Reference Device:

- Patient Specific 3D Printed Bone Segments Additive Orthopaedics, LLC (K180239)
- Vantage PSI System, 3D Systems, Inc. (K193432)

The predicate devices have not been the subject of any design related recall.

5. DEVICE DESCRIPTION

The Paragon 28 Patient Specific Marking Guides are designed and additively manufactured based on an individual patient's CT scan(s). In surgery, these guides, templates, or anatomical models are used to assist a surgeon in guiding the marking of a bone and/or guiding a surgical instrument for placement (i.e., placing a k-wire). The guides are not used for cutting bone. All guides are patient specific and utilize a CT scanning protocol previously cleared in K180239 (Paragon 28 formerly Additive Orthopaedics). The anatomical landmarks necessary for the design and creation of the Patient Specific Marking Guides must be present and identifiable on computed tomography scan.

The Paragon 28 Patient Specific Marking Guides are additively manufactured from biocompatible nylon (PA 2200 – polyamide 12 white) and produced by laser sintering. The Patient Specific Marking Guides are optional for surgeons to help visualize and plan osteotomies in the foot and ankle and are for single use only.

6. INDICATIONS FOR USE

The Paragon 28 Patient Specific Marking Guide is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies for adult patients in the foot and ankle. The Patient Specific Guide is not intended to directly guide the cutting of bone. The device is single use only.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTI S WITH THE PREDICATE DEVICE

Technological Characteristics Comparison

The Patient Specific Marking Guides and the legally marketed predicate devices have similar indications, and manufacturing process. The dimensions and geometry of the Patient Specific Marking Guides are patient specific, utilizing a previously cleared CT scanning protocol. Both the subject and predicate devices' dimensions and geometry are made based on the patient's anatomy.

Substantial Equivalence Non-Clinical Evidence

The intended use and technological characteristics of the subject device are substantially equivalent to the predicate device. The potential impact of a technological difference, for instance polymeric material grade, was addressed by the biocompatibility testing per ISO 10993-1.

8. SUMMARY OF PERFORMANCE TESTING

The testing outlined below was intended to show that the output of the design and development process demonstrated compliance with the device specifications. Biocompatibility testing was conducted to prove the device is not toxic and safe for limited (<24 hours) contact. In addition, a cadaver lab were conducted to prove the subject device performs in accordance with its intended use. The following testing was conducted or referenced for the Patient Specific Marking Guides:

- Sterilization Validation
- Equipment Qualification (IQ/OQ/PQ)
- Cleaning Validation
- Biocompatibility Testing
- Cadaver Study
- Distribution Testing
- Packaging Validation
- Aging Study

9. CONCLUSION

The Paragon 28 Patient Specific Marking Guides have the identical technologic characteristics of the predicate devices. These characteristics include the intended use, basic design, use of polymeric materials, additive manufacturing process, and fundamental technology. The design characteristics of the subject system raises no new safety and effectiveness questions. From the evidence submitted in this 510(k), the subject devices can be expected to perform the same as the predicate device.