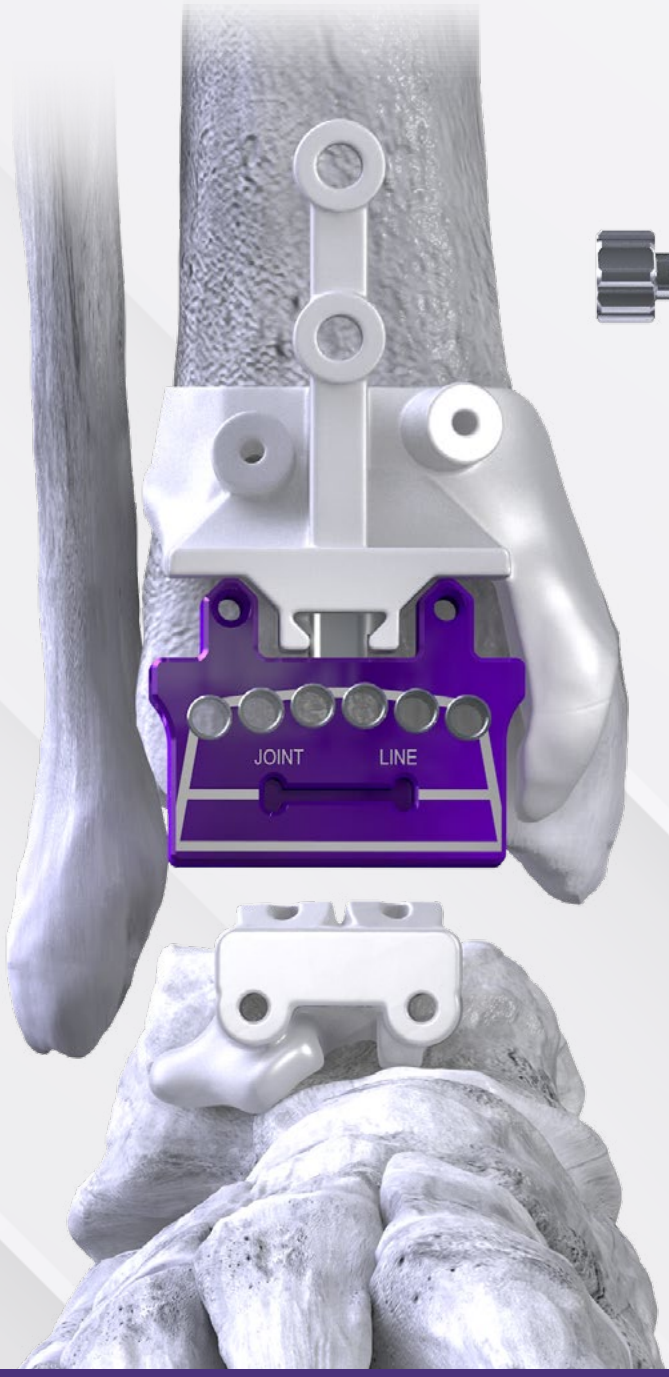
MAVEN™

PATIENT SPECIFIC SURGERY

FEATURING NEW TO MARKET

AP Positioning Technology



Exclusively foot & ankle 2nd Paragon®

PATIENT-SPECIFIC INSTRUMENTATION

FACILITY REGISTRATION PACKET

APEX 3D™ TOTAL ANKLE REPLACEMENT

Powered by MAVEN™

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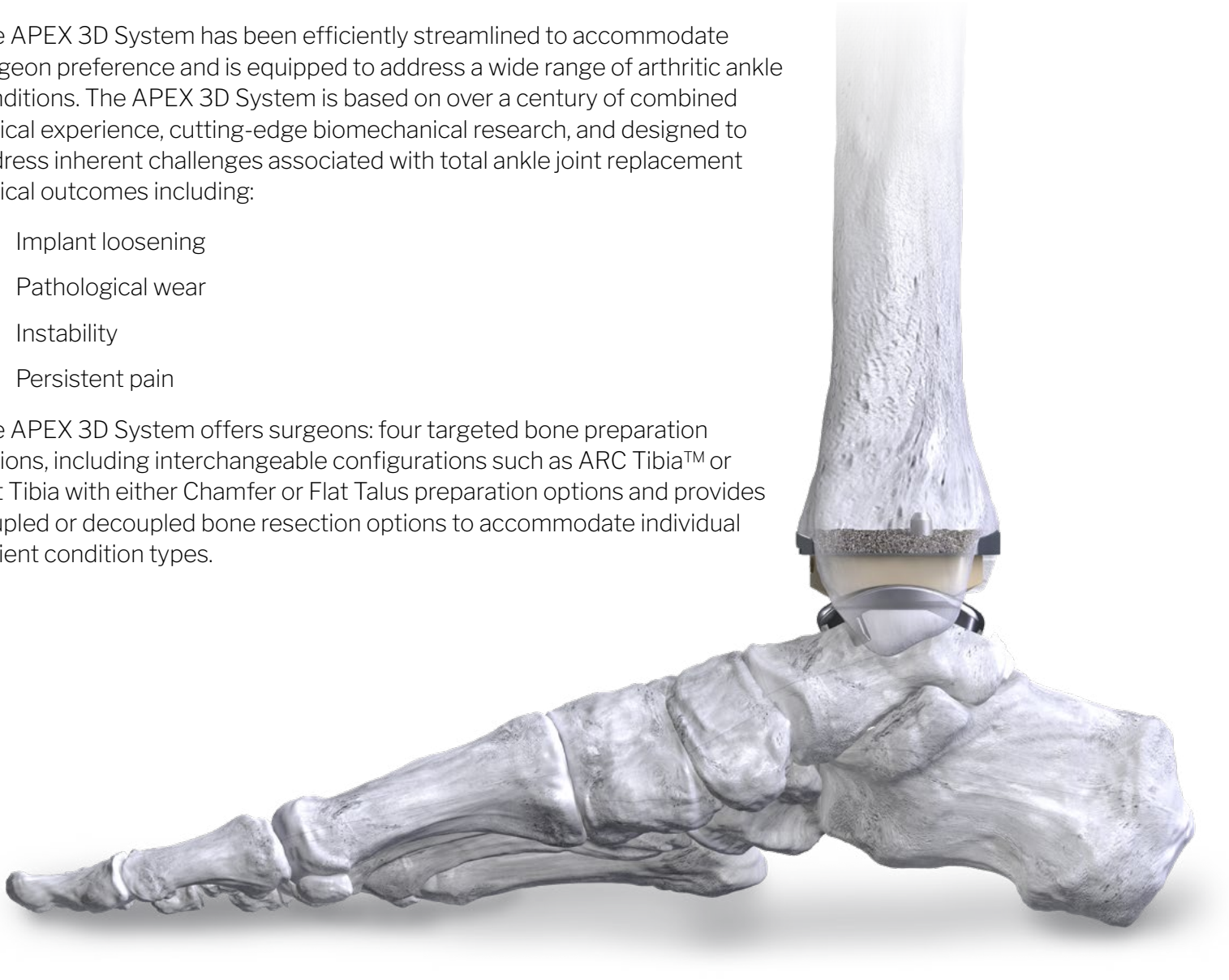
The MAVEN Patient-Specific Instrumentation System and Surgical Planning Case Reports are currently designed exclusively for the Paragon 28® APEX 3D Total Ankle Replacement System. MAVEN PSI Surgical Planning Case Reports and PSI Guides are based on surgeon-approved inputs. MAVEN PSI 3D Printed Nylon surgical instruments are designed for single use only. The MAVEN PSI surgical instruments are supplied clean, non-sterile, and must be sterilized before use. Caution: Federal law restricts this device to sale by or on the order of a physician.

Paragon 28® is pleased to announce the release of the MAVEN™ Patient-Specific Instrumentation (PSI) System. The MAVEN PSI System was developed to expedite positioning of the APEX 3D™ Total Ankle Replacement System and designed to accurately determine both implant size selection and placement critical for long-term survivorship.[1] The release of the MAVEN PSI System and APEX 3D System complements the Gorilla® Ankle Fracture Plating System, Silverback® Fusion Plating System, Phantom™ Hindfoot TCC and ActivCore™ Nail Systems.

The APEX 3D System has been efficiently streamlined to accommodate surgeon preference and is equipped to address a wide range of arthritic ankle conditions. The APEX 3D System is based on over a century of combined clinical experience, cutting-edge biomechanical research, and designed to address inherent challenges associated with total ankle joint replacement clinical outcomes including:

- Implant loosening
- Pathological wear
- Instability
- Persistent pain

The APEX 3D System offers surgeons: four targeted bone preparation options, including interchangeable configurations such as ARC Tibia™ or Flat Tibia with either Chamfer or Flat Talus preparation options and provides coupled or decoupled bone resection options to accommodate individual patient condition types.



The APEX 3D System consists of cemented, fixed bearing, anatomically contoured implant components, intuitive instrumentation and precision bone resection guides intended for use in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery is also indicated when sufficient bone stock is present. Components are intended for cemented use only.

For additional information regarding Indications for Use, Contraindications, Warnings, Precautions, etc. please visit: Paragon28.com/ifus/.

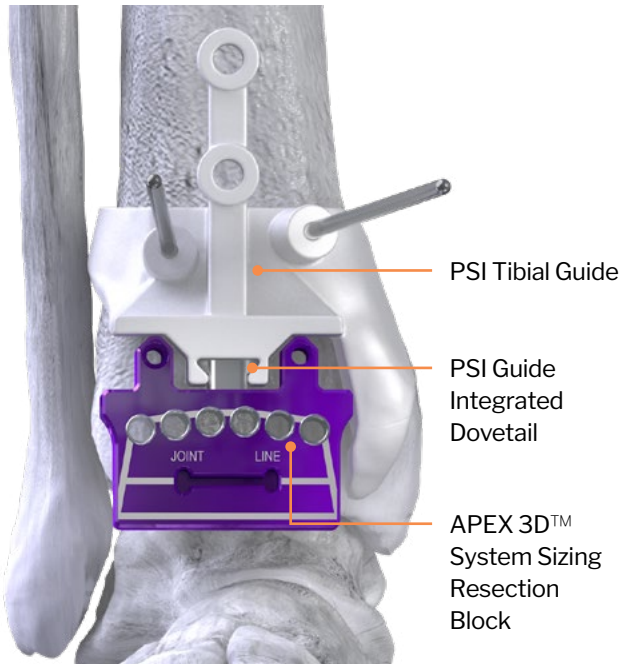
THE MAVEN™ PSI SYSTEM...

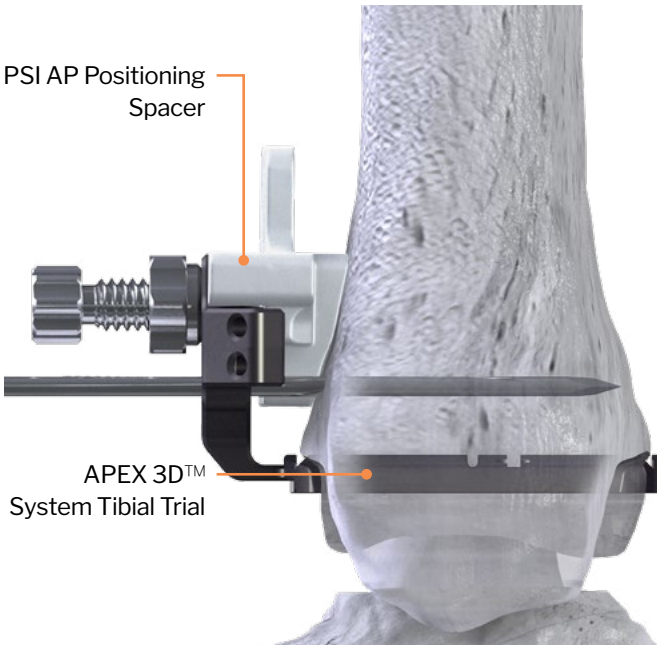
Provides an accurate and simple-to-use technology in the palm of your hand. The Patient-Specific Guides, Surgical Planning Case Reports and Bone Models are based on individual patient anatomic structures, are generated using segments of the patient's operative limb CT scan and are intended to contour to the patient's anatomy.

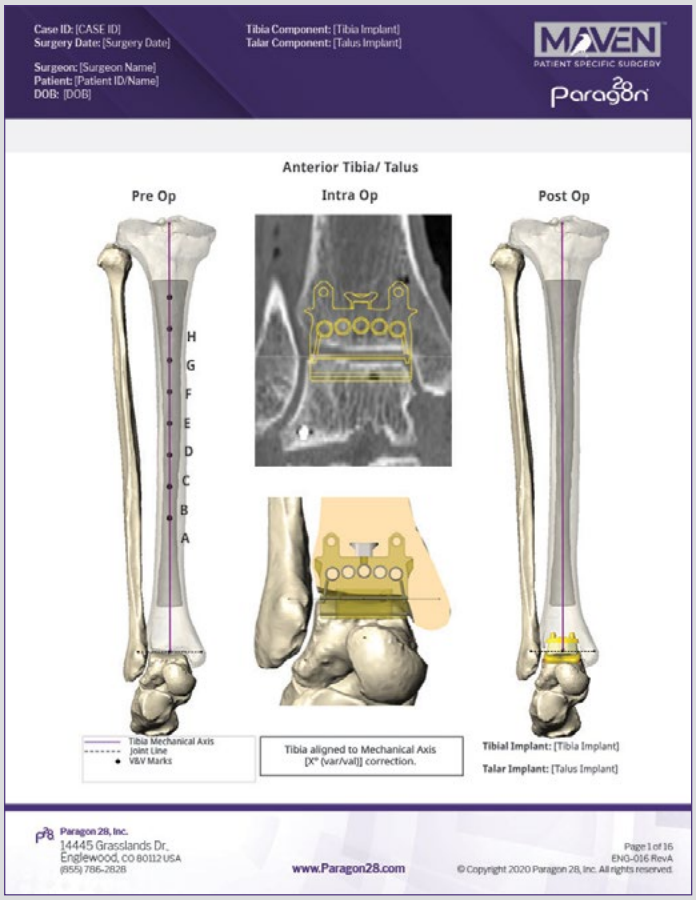
The MAVEN PSI System utilizes computer assisted processing technology to achieve accurate tibiotalar alignment and implant placement to reduce potential for eccentric loads, wear debris and osteolysis.[1,2] The System was also designed to address abnormal varus or valgus alignment of the implant construct, reported to be a major cause of implant loosening[3] and decreased postoperative function.[4]

MAVEN PSI SYSTEM GUIDES...

- Expedite and simplify alignment
- Utilize an advanced CT based coordinate system designed for precise component alignment, accurate implant placement and size selection critical for long term survivorship[5]
- Are designed based on individual patient anatomic structures to ensure the Guides contour to the patient's bone geometry not osteophytes
- Preserve periosteum and anterior talar cartilage during joint preparation due to minimal Guide/bone contact interface
- Provide secure and stable tactile feedback during initial positioning
- Feature a Medial Malleolus Wrap designed to reinforce stability during Guide fixation
- Are designed to preserve anatomic landmark references and reduce potential for alignment induced bone resection errors
- Allow for precise component positioning and establishes clearly defined bone resection planes
- New to market AP Positioning Technology simplifies the time-consuming sizing evaluation of the tibial component, reduces potential guess work and establishes optimal bone coverage
- Feature a lateral talar wrap that extends laterally to establish a stable foundation during Guide fixation
- Include streamlined conversion points for refined positioning and micro adjustments

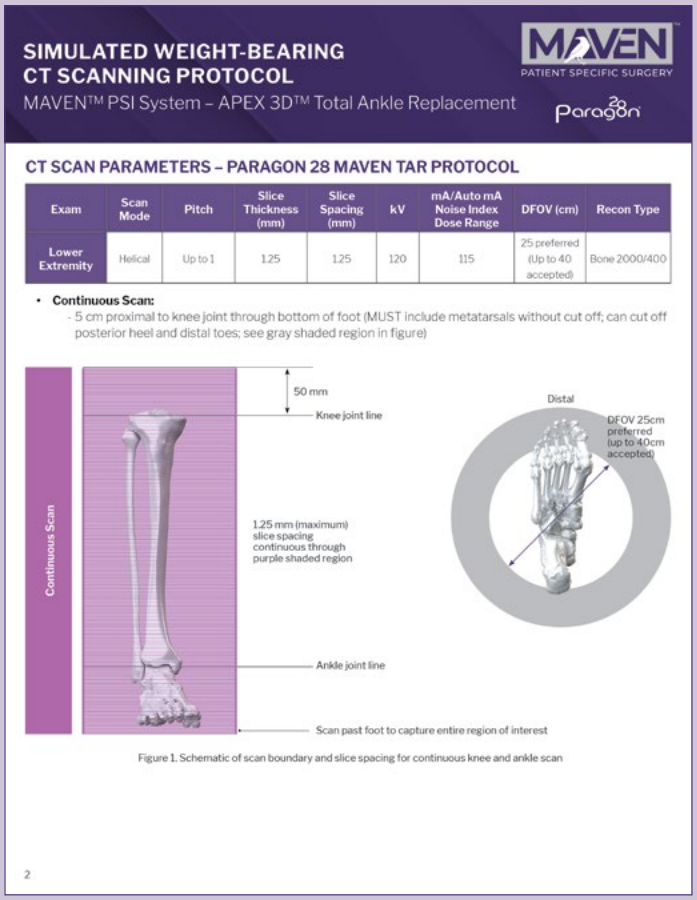






SURGICAL PLANNING CASE REPORTS...

- Are generated based on surgeon-approved inputs and segments of the patient's CT scanned anatomy
- Address all 6 degrees of rotational and translational orientation
- Allow for enhanced pre-operative visualization of anatomic structures, bone resection levels and help to identify anatomic abnormalities
- Depict ideal implant size selection, placement and optimal A/P tibial bone coverage based on the patient's anatomy



CT SCANNING PROTOCOLS...

- Are available in both weight-bearing and simulated weight-bearing scanning options
- Provide a comprehensive continuous knee to ankle scan through bottom of foot
- Incorporate 1.25 mm (maximum) slice spacing for optimal resolution
- Successfully utilizing the MAVEN™ PSI System requires adhering to the MAVEN CT Scan Protocols.
- Facilities conducting the CT scans are required to follow the specific instructions to reduce potential for scan rejections during segmentation and processing
- The necessary scanning parameters are depicted within the documents and can be found on our website: *www.apexankle.com*

CASE & TRAY COMPONENTS

PART NUMBER	ALIGNMENT CASE INSTRUMENT DESCRIPTIONS	QTY PER SET
P10-944-PSI0	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 1N	1
P10-944-PSI1	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 1	1
P10-944-PSI2	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 2	1
P10-944-PSI3	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 3	1
P10-944-PSI4	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 4	1
P10-944-PSI5	APEX 3D-PS Total Ankle Replacement System, Talar PSI Resection Block, Size 5	1
P10-941-PSI1	APEX 3D-PS Total Ankle Replacement System, V-V Alignment Guide	1

PATIENT SPECIFIC INSTRUMENTATION

PART NUMBER	ALIGNMENT CASE INSTRUMENT DESCRIPTIONS	QTY PER SET
P10-PSI-0001	MVN PSI Case Report, Tibial and Talar Guides	1
P10-PSI-0002	MVN PSI Case Report, Tibial Guides	1
P10-PSI-0003	MVN PSI Case Report Only	1

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

MAVEN™ PATIENT-SPECIFIC INSTRUMENTATION INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The MAVEN™ Patient-Specific Instrumentation System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The MAVEN™ Patient-Specific Instrumentation System is intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The MAVEN™ Patient-Specific Instrumentation System is intended for single use only. The MAVEN™ Surgical Planning Case Reports are intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

CONTRAINDICATIONS

All applications of the MAVEN™ PSI System that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by

- Patients with significant changes to anatomy occurring after the medical scan used for product definition was obtained. Surgery should occur no later than one year after the patient scans.

WARNING AND PRECAUTIONS

- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides prior to use.
- To avoid serious injury, patient identification on guides and reports must be verified and confirmed against patient identification prior to use.
- Device(s) are single use only and designed for use with a specific patient only. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.
- Guides are designed for a specific patient. To avoid the potential for serious injury, guides should not be modified in any way.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or case reports. Inspect all components preoperatively to assure utility. Inspect holes to ensure no debris is present.
- MAVEN™ PSI guides are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
- These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device.
- The surgeon is held liable for complications associated with incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.
- Do not to drop or contaminate the device during surgery.
- Improper placement, positioning, and fixation of the instruments may result in unusual stress conditions and a subsequent reduction in service life of the total ankle replacement components.
- **Do not use other manufacturer's instruments or implants in conjunction with the MAVEN™ PSI System**

January 14, 2021

Paragon 28, Inc.
% Dave McGurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K202019
Trade/Device Name: Paragon 28 MAVEN™ Patient-Specific Instrumentation
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN, OYK
Dated: December 8, 2020
Received: December 9, 2020

Dear Dave McGurl:

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,

Ting Song -S

Ting Song, Ph.D., R.A.C.
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

MAVEN™

PATIENT SPECIFIC SURGERY

APEX 3D™

TOTAL ANKLE REPLACEMENT

Powered by MAVEN™

P10-HRM-0002 Rev. B [2022-02-04]

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Exclusively foot & ankle

Paragon 28®

www.Paragon28.com

References

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4. Rhoads DD, Noble PC, Reuben JD, Mahoney OM, Tullos HS. The effect of femoral component position on patellar tracking after total knee arthroplasty. Clinical orthopaedics and related research. 1990 Nov 1(260):43-51.
5. Insall JN, Binazzi R, Soudry M, Mestriner LA. Total knee arthroplasty. Clinical orthopaedics and related research. 1985 Jan 1(192):13-22.