November 9, 2020

3D Systems
Kim Torluemke
Vice President, Quality & Regulatory, Healthcare
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K193432
Trade/Device Name: Vantage PSI System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: OYK
Dated: November 5, 2020
Received: November 6, 2020

Dear Kim Torluemke:

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, PhD, RAC
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193432

Device Name
Vantage PSI System

Indications for Use *(Describe)*

The Vantage PSI System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The Vantage PSI System is intended for use with Exactech's Vantage Total Ankle System and its cleared indications for use.

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.

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510(K) SUMMARY

1. INTRODUCTION

This document contains the 510(k) summary for the Vantage™ PSI System. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: Medical Modeling - A 3D Systems Company

Address: 5381 South Alkire Circle
Littleton, CO 80127, USA
Phone: (720) 643-1001
Fax: (720) 643-1009

Official Contact: Kim Torluemke
Vice President, Quality and Regulatory, Healthcare

Date Prepared: November 5, 2020

3. DEVICE

Trade Name: Vantage PSI System

Common Name: Ankle surgical guide system

Classification Name: Ankle Arthroplasty Implantation System

Classification: Class II, 21 CFR 888.3110

Product Code: OYK

4. PREDICATE DEVICES

Predicate device:

- PROPHECY® INVISION® Preoperative Navigation Alignment Guides, Wright Medical Technology, Inc.(K170968)

Reference devices:

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

5. DESCRIPTION OF THE DEVICE

3D System's Vantage PSI System is patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides and models are designed and manufactured from patient imaging data (CT) and are made from biocompatible nylon. The surgical guides in combination with Exactech Vantage Total Ankle reusable instruments, facilitate the positioning of

Vantage Total Ankle Implants. 3D System's Vantage PSI System produces a variety of patient specific outputs including surgical guides, anatomic models, and case reports for use with Exactech's Vantage Total Ankle System (K152217 and K183343).

6. INTENDED USE

The Vantage PSI System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The Vantage PSI System is intended for use with Exactech's Vantage Total Ankle System and its cleared indications for use.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use and technological characteristics of the subject device (Vantage PSI System) are either identical or substantially equivalent to the predicate device (PROPHECY® Preoperative Navigation Alignment System):

The principles of operation and technological characteristics are all substantially equivalent between the Vantage PSI System and the identified predicate device. Specifically, the predicate device includes 3D printing of patient specific anatomical models and surgical guides with polyamide materials. Both have stainless steel accessories produced from a common subtractive manufacturing process.

The Vantage PSI System uses the same fundamental technologies as its predicate device. These include image transformation and manipulation via software that is subsequently used for 3D printing of anatomical models and guides and for surgical planning, only potentially differing in the software applications.

The outputs of the Vantage PSI System include materials commonly used in surgical instruments (stainless steel) and for surgical guides and anatomical models (biocompatible polyamide). These materials are substantially equivalent to those employed by the predicate, which also uses a polyamide material and stainless steel surgical instruments.

The Vantage PSI System Accessories are standardized stainless steel fluoroscopic inserts that are inserted into patient-specific guides to assist in alignment operations. The accessories are similar to those included with the predicate device, but differ in shape. The predicate device utilizes standard surgical pins. The subject device includes a specific single use tool to be used exclusively with the system. These accessories are sterilized by the healthcare facility with the same cycle as the other system outputs. The minor differences in accessory geometry does not change the intended use of the system, and does not raise new questions of safety and effectiveness.

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. Bench and cadaveric testing was conducted to prove the subject device performs in accordance with its intended use and is substantially equivalent to the listed predicate device.

The following testing was conducted in accordance with the listed consensus standards for the Vantage PSI System:

- **Process Qualification**
  Process qualification was conducted to assess the manufacturing process as well as operator repeatability within the digital workflow. Cases utilized for testing were representative of ankle reconstruction procedures within the subject device's intended use. Both digital and physical outputs from all manufacturing processes were verified against design specifications. All test method acceptance criteria were met.
- **Cleaning Validation**
  Cleaning validations were performed in accordance with AAMI TIR 30. Following soiling and cleaning of the subject devices, bioburden, protein levels, and hemoglobin levels were examined. All test method acceptance criteria were met.
- **Sterilization Validation**
  Steam sterilization validations were performed for the dynamic-air-removal cycle in accordance with ISO 17665-1:2006 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. All test method acceptance criteria were met.
- **Biocompatibility Validation**
  Biocompatibility endpoints were evaluated in accordance with ISO 10993-1. The battery of cytotoxicity, sensitization, irritation, and acute systemic toxicity testing conducted on the subject devices manufactured from polyamide and titanium alloy are within the pre-defined acceptance criteria. The results of the testing adequately address biocompatibility for the output devices and their intended use.
- **Packaging Validation**
  Packaging validation was performed on all packaging configurations of the system. Testing was performed in accordance with the 3D Systems Transportation Test Standard (based on ASTM and National Motor Freight Classification standards). All test method acceptance criteria were met.
- **Shelf Life Validation**
  Shelf life validation was conducted in accordance with ASTM F1980-16 to verify the stated shelf life duration. All test method acceptance criteria were met.
- **Debris Validation**
  Debris generation validation was performed utilizing standard orthopedic instrumentation. Debris generation was evaluated and compared to published data. The results of the testing perform equivalent or better than the values found in literature.

- **Cadaver Study / Design Validation**
  Cadaveric and design validation studies were performed to compare the subject device to Vantage Total Ankle standard instrumentation. The cadaver and design validation studies utilized three surgeon users. 2D analysis was conducted by measuring AP tibia varus/valgus, bearing-to-bearing, and lateral tibia from intra-operative fluoroscopic images, and compared to the pre-operative plan. 3D analysis was conducted by comparing final implant placement to pre-operative implant placement. The 3D analysis consisted of post-operative CT image segmentation, STL alignments, and measurements. Translations were analyzed across three axis (medial/lateral, anterior/posterior, and distal/proximal) and rotations were analyzed across three axis (varus/valgus, plantarflexion/dorsiflexion, and internal/external). The results of both 2D and 3D analysis demonstrate the subject device performing equivalent or better than the Vantage Total Ankle standard instrumentation.

Summary

All design, process, and other verification and validation testing, which were conducted as a result of risk analyses and design impact assessments, showed conformity to pre-established specifications and acceptance criteria. The acceptance criteria was established in support of device performance, and testing demonstrated substantial equivalence of the system to the predicate device.

9. CONCLUSION

Based on a comparison of the intended use and technological characteristics, the Vantage PSI System is substantially equivalent to the identified predicate device. Minor differences in the indications for use, technological and performance characteristics do not raise new or different questions of safety and effectiveness. Additionally, the non-clinical testing supports that the system performs in accordance with its intended use and is as safe, as effective, and performs as well as the predicate device.