June 30, 2023

3D Systems, Inc.
Ashley Dawson
Director, Regulatory Affairs
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K231585
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: May 31, 2023
Received: May 31, 2023

Dear Ashley Dawson:

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,

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231585

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 intra-operatively, 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.

510(k) Summary

Prepared on: 2023-05-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	3D Systems, Inc.
Applicant Address	5381 South Alkire Circle Littleton CO 80127 United States
Applicant Contact Telephone	+1 803-326-3908
Applicant Contact	Dr. Ashley Dawson
Applicant Contact Email	ashley.dawson@3dsystems.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vantage PSI System
Common Name	Ankle joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Ankle Arthroplasty Implantation System
Regulation Number	888.3110
Product Code	OYK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193432	Vantage PSI System	OYK

Device Description Summary

21 CFR 807.92(a)(4)

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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 intra-operatively, 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use is the same as the predicate device: 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 intra-operatively, 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.

Technological Comparison

21 CFR 807.92(a)(6)

The principles of operation and technological characteristics are substantially equivalent between the subject Vantage PSI System and the predicate Vantage PSI System (K193432). Both the predicate and the subject devices are designed with CT-based methods to produce a patient specific instrument. Vantage PSI System Guides and models are manufactured using SLS technology with DuraForm®

ProX PA (polyamide) material. Both the subject and predicate devices guide the placement of pins and resections of tibial and talar anatomies for total ankle arthroplasties intended for use with Exactech's Vantage Total Ankle System and its cleared indications for use. The differences between the subject Vantage PSI System and the predicate Vantage PSI System are additional fixation options, addition of corner drill features, and an optional decoupled talus guide. The reason for the changes is to align with updates to the Exactech Vantage Total Ankle System. The changes included in the subject Vantage PSI System are not technologically different from the predicate Vantage PSI System.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Cadaveric comparison testing was performed between the subject and predicate device and Exactech instrumentation. Accuracy and functionality were shown to be substantially equivalent across all devices and instruments.