November 10, 2021

3D Systems
Ben Johnson
Vice President, Portfolio & Regulatory, Healthcare
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K211244
Trade/Device Name: VSP Orthopedics
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: October 12, 2021
Received: October 14, 2021

Dear Ben Johnson:

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 and Part 809); 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)*

K211244

Device Name
VSP® Orthopedics System

Indications for Use *(Describe)*

The VSP® Orthopedics System 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 distal femur, tibia, and non-sacrum pelvis.

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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510(K) SUMMARY

1. INTRODUCTION

This document contains the 510(k) summary for the VSP® Orthopedics System. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: 3D Systems, Inc.

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

Official Contact: Scott Brewer
Director, Regulatory Affairs, Healthcare

Date Prepared: April 23, 2021

3. DEVICE

Trade Name: VSP® Orthopedics System

Common Name: Patient specific orthopedic anatomical models, templates, guides, and surgical plans.

Classification Name: Orthopaedic Surgical Planning and Instrument Guides

Classification: Class II, 21 CFR 888.3030

Product Code: PBF

4. PREDICATE DEVICES

Predicate device:

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

5. DESCRIPTION OF THE DEVICE

The VSP® Orthopedics System is intended to assist a surgeon with pre-operative planning and transfer of the pre-operative plan to the surgery in orthopedic procedures. The system contains several physical and digital outputs including patient-specific anatomical models, templates, and guides (physical outputs); and patient-specific surgical plans and digital files (digital or documentation outputs).

Outputs of the VSP® Orthopedics System are designed with physician input and reviewed by the physician prior to finalization and distribution.

The VSP® Orthopedics System also contains Stainless Steel Drill Inserts (VSP® Orthopedics System Accessories) which are intended to be used by the physician to guide drilling activities during the

surgical procedure. The inserts fit into a standard hole in the cutting / drill guides and can be used across all VSP® Orthopedics System guides and templates.

6. INTENDED USE

The VSP® Orthopedics System 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 distal femur, tibia, and non-sacrum pelvis.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use and technological characteristics of the subject device are either identical or substantially equivalent to the predicate device (VSP® Orthopedics System), differing only in the expansion of materials included within the VSP® Orthopedics System for anatomic models. The potential impact on substantial equivalence of each technological difference was addressed by risk analysis and verification and validation testing.

Similarities to Predicate

The inputs to the subject device are identical to those of the predicate device. System outputs of the subject and predicate device comprise both digital and physical outputs which can include patient-specific anatomical models, and guides for the purpose of assisting the surgeon during maxillofacial surgeries. The subject device and the predicate device are both intended to be generated by trained personnel, in a non-medical manufacturing or office environment, with active support from the surgeon. The subject device uses the same technologies as the predicate device. These include image transfer and manipulation via software that is subsequently used for 3D printing of anatomical models and guides for surgical planning. The subject and predicate device use the same software components for the digital workflow. There has been no change to the sterilization process for the surgical guides produced by the subject device. The subject device serves the same patient population as the predicate device.

Differences to Predicate

One new material is presented in the modified system and makes up the changes presented within this Traditional 510(k) submission. The material, SLA printing resin Accura ClearVue, is being added to the system for anatomical models.

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. Non-clinical 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 for the VSP® Orthopedics System:

- Operational Qualification
  A process operational qualification was performed to assess the manufacturing process over the range of allowable process parameters. All test method acceptance criteria were met.
- Performance Qualification
  A process performance qualification was conducted to assess the manufacturing process repeatability at nominal parameters. All test method acceptance criteria were met.
- Cleaning Validation
  A cleaning validation was performed in accordance with AAMI TIR 30. Following soiling and cleaning of the subject device, bioburden, protein levels, and hemoglobin levels were exampled. 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. Sensitization, irritation, and acute systemic toxicity testing conducted on the subject device manufactured from Accura ClearVue are within the pre-defined acceptance criteria. The results of the testing adequately address biocompatibility for the output device and it's intended use.
- Shelf Life Validation
  A shelf life validation was performed to ensure Accura ClearVue anatomical model outputs maintain functionality following a shelf life of 3 months.
- Clinical Performance Data
  Clinical testing was not necessary for the determination of substantial equivalence.

All process and 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

The VSP® Orthopedics System has the same intended use and similar technological characteristics as the predicate. Minor differences in the technological and performance characteristics do not raise new or different questions of safety and effectiveness.