April 26, 2021

3D Systems
Scott Brewer
Director, Regulatory Affairs, Healthcare
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K210347
Trade/Device Name: VSP® System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: February 5, 2021
Received: February 8, 2021

Dear Scott Brewer:

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 Michael Adjodha
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K210347

Device Name
VSP® System

Indications for Use *(Describe)*

The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

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 – K210347

1. INTRODUCTION

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

2. SUBMITTER

Name: 3D Systems

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® System

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

Classification Name: Bone Cutting Instruments and Accessories
Classification: 21 CFR 872.4120

Class: Class II

Product Code: DZJ

Subsequent Product Code: LLZ

4. PREDICATE DEVICES

Predicate device:

- VSP® System, Medical Modeling a 3D Systems Company (K192192)

5. DESCRIPTION OF THE DEVICE

The VSP® System utilizes a combination of Commercial Off-The-Shelf (COTS) and custom software to manipulate 3D medical images (CT based systems) to create virtual and physical anatomical models, templates, surgical guides, and surgical plans for reconstructive surgical procedures.

6. INTENDED USE

The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces

physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

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® System), differing only in the expansion of materials included within the VSP® System for anatomic models to include Accura® ClearVue™. The potential impact on substantial equivalence of each technological difference was addressed by risk analysis and verification and validation testing.

Table 1: Substantial Equivalence Comparison

Specification / Characteristic	Subject Device, VSP® System, Medical Modeling a 3D Systems Company	Predicate Device, VSP® System, Medical Modeling Inc. (K192192)	Comparison
Classification	21 CFR 872.4120, 21 CFR 892.2050	21 CFR 872.4120, 21 CFR 892.2050	Substantially Equivalent
Class	II	II	Substantially Equivalent
Product Code	DZJ, LLZ	DZJ, LLZ	Substantially Equivalent
Indications for Use	The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	Substantially Equivalent
Technological Description	Software / Hardware based device that incorporates image manipulation software to transfer, segment and modify images with input from the physician that are further used to manufacture, via rapid prototyping, anatomical models and surgical guides. Additional system outputs include digital files and surgical case planning reports. Device includes image processing software, hardware for rapid prototyping of physical outputs, and the resulting anatomical models and surgical guides.	Software / Hardware based device that incorporates image manipulation software to transfer, segment and modify images with input from the physician that are further used to manufacture, via rapid prototyping, anatomical models and surgical guides. Additional system outputs include digital files and surgical case planning reports. Device includes image processing software, hardware for rapid prototyping of physical outputs, and the resulting anatomical models and surgical guides.	Substantially Equivalent

Specification / Characteristic	Subject Device, VSP® System, Medical Modeling a 3D Systems Company	Predicate Device, VSP® System, Medical Modeling Inc. (K192192)	Comparison
Software Technologies	Image transformation into 3D models, Computer Aided Design, Surgical planning / simulation	Image transformation into 3D models, Computer Aided Design, Surgical planning / simulation	Substantially Equivalent
Hardware Technologies	3D Printing to produce physical output devices	3D Printing to produce physical output devices	Substantially Equivalent
System Inputs	DICOM file from Medical Scanner (CT, CBCT), patient contoured and standard implant .STL files; input from physician	DICOM file from Medical Scanner (CT, CBCT), patient contoured and standard implant .STL files; input from physician	Substantially Equivalent
Technologies Employed	Software, 3D Printing	Software, 3D Printing	Substantially Equivalent
Materials	– Accura ClearVue Epoxy/Resin Acrylic (photopolymer): Stereolithography (SLA) – Accura SL 7810M Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Somos BioClear Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Accura Y-C 9300M Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Ti-6Al-4V: Direct Metal Printing – Polyamide: Selective Laser Sintering	– Accura SL 7810M Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Somos BioClear Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Accura Y-C 9300M Epoxy/Resin, Acrylic (photopolymer): Stereolithography (SLA) – Ti-6Al-4V: Direct Metal Printing – Polyamide: Selective Laser Sintering	Substantially Equivalent
Method of Sterilization	Steam sterilization 1 x 10^{-6} SAL	Steam sterilization 1 x 10^{-6} SAL	Substantially Equivalent
Physician Interaction with Planning and Physician Model / Guide Approval	Yes	Yes	Substantially Equivalent

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 are comprised of both digital and physical outputs, which can include patient-specific anatomical models, guides, and splints for the purpose of assisting the surgeon during maxillofacial surgeries. The subject device and the predicate device are both intended to be used by trained personnel, in a non-medical manufacturing or office environment, with active support from the surgeon. The subject device uses the same fundamental technologies as the predicate device. These include image transfer and manipulation via software that is subsequently used for 3D printing of anatomical models, guides, and splints and 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 and templates 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 anatomic 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 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 its intended use.
- **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 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. Therefore, the subject device is substantial equivalence to the predicate device.