February 26, 2020

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

Re: K192192
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
Dated: January 24, 2020
Received: January 28, 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192192

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192192

510(K) SUMMARY

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:	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:	February 24, 2020

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. System, Image Processing, Radiological
Classification:	Class II, 21 CFR 872.4120
Product Code:	DZJ
Subsequent Product Code:	LLZ

4. PREDICATE DEVICES

Predicate device:

- VSP® System, Medical Modeling a 3D Systems Company (K133907)

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. The following table provides a list of VSP System outputs by material and function.

Category	Material	Guide Function
Marking Guide	• Duraform ProX PA • Ti-6Al-4V	Marking of maxillofacial bone
		Marking of graft bone
Cutting Guide	• Ti-6Al-4V	Cutting/drilling/marking of maxillofacial bone
		Cutting/drilling/marking of graft bone
Positioning Guide	• Duraform ProX PA • Ti-6Al-4V	Positioning of maxillofacial bone

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 to include Polyamide for marking guides and Titanium Alloy for marking, cutting and drilling guides within the VSP System. 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, 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, templates and anatomical models produced by the subject device. The subject device serves the same patient population as the predicate device.

Differences to Predicate

Two new materials are presented in the modified system and make up the modification of this Traditional 510(k) submission. Two additional 3D printing technologies have been added to the system in support of the additional materials. The VSP System stainless steel cutting and drill guide tool accessories are not changing, however, these accessories will not be utilized with the polyamide and titanium alloy surgical guide materials. The polyamide guides will not include features that interface with cutting or drilling surgical tools. This presented no issues of safety and/or effectiveness during validation, and the data obtained demonstrated the system performed correctly and in accordance with its intended use without the use of the stainless steel accessories, noting the aforementioned limitation of the polyamide guides.

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:

- **Design Validation**
  Design validation was performed to ensure VSP System guide designs conform to the user needs and intended use of supporting maxillofacial surgeries. The test methods assessed accuracy of cutting location/trajectory, drilling location/trajectory, and bony segment length utilizing subject device guides on bone models. The results of the testing concluded that all acceptance criteria were met.
- **Process Performance Qualification**
  A process performance qualification was conducted to assess the manufacturing process as well as operator repeatability within the digital workflow. Cases utilized for testing were representative of orthognathic and 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.

- **Mechanical Performance Validation**
  Material testing was conducted on the subject device guide materials to compare performance against the predicate device. Flexural deformation testing per ASTM D790, ASTM E290, and ISO 178 was conducted on both subject and predicate devices and compared. The results of the testing concluded that subject devices perform equivalent or better than the predicate device.
- **Packaging Validation**
  Packaging validation was performed on all packaging configurations of the VSP 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.
- **Clinical Performance Data**
  Clinical testing was not necessary for the determination of substantial equivalence.

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

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. 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.