K133907

JAN 2 2 2014

SECTION 7: 510(K) SUMMARY

1 INTRODUCTION

1.1 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 APPLICANT NAME AND ADDRESS

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Phone: (303) 273-5344
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Official Contact: Andrew Christensen
President

Summary Preparation Date: December 23, 2013

3 DEVICE NAME AND CLASSIFICATION

Trade Name: VSP® System

Common Name: System for the creation of patient specific anatomical models, templates, guides, and surgical plans

Classification Name: Bone Cutting Instrument and Accessories

Classification: Class II, 21 CFR 872.4120

Product Code: DZJ, LLZ

4 PREDICATE DEVICES

4.1 The modified VSP® System is claimed to be substantially equivalent to the following legally marketed predicate device:

4.1.1 VSP® System, Medical Modeling Inc. (K120956)

5 PERFORMANCE STANDARDS

5.1 There are no performance standards for this device type.

6 INDICATIONS FOR USE

6.1 The Medical Modeling 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 DESCRIPTION OF THE DEVICE

7.1 The Medical Modeling VSP® System is a collection of software and associated additive manufacturing (rapid prototyping) equipment intended to provide a variety of outputs to support orthognathic or reconstructive surgery. The system uses electronic medical images of the patient's anatomy with input from the physician, to manipulate original patient images for planning and executing surgery. The system produces a variety of patient specific outputs including, anatomical models (physical and digital), surgical templates / guides, splints, and patient specific case reports.

7.2 Following the Medical Modeling Quality System and specific Work Instructions, trained employees utilize a combination of Commercial Off-The-Shelf (COTS) and custom software to manipulate 3D medical scan images which can include Computed Tomography (CT), Cone Beam CT (CBCT), 3D scan images from patient physical models (stone models of the patient's teeth), and / or standard (non-bent) or patient contoured implant files to create patient-specific physical and digital outputs. The process requires clinical input and review from the physician during planning and prior to delivery of the final outputs. While the process and data-flow can vary somewhat based on the particular requirements of a given patient and physician, the following description outlines the functions of key sub-components of the system, and how they interact to produce the defined system outputs. It should be noted that the system is operated only by trained Medical Modeling employees, and the physician does not directly input information. The physician only provides input for model manipulation and interactive feedback through viewing of digital models of system outputs that are modified by the engineer during the planning session.

7.3 The VSP® System is made up of 14 individual pieces of software and additional manufacturing equipment integrated to provide a range of anatomical models (physical and digital), surgical templates / guides and patient-specific case reports for reconstructive surgery in the maxillofacial region. Surgical guides for graft bone harvesting from patient bone such as, but not limited to, the fibula and hip, are also produced by the system.

7.4 The VSP® System requires an input 3D image file from medical imaging systems (i.e. CT) and / or a standard or patient contoured implant file. This input is then used, with support from the prescribing physician to provide the following categories of outputs to support reconstructive surgery. Each system output is designed with physician input, and reviewed by the physician prior to finalization and distribution. All outputs are used only with direct physician involvement to reduce the criticality of the outputs.

7.5 System Outputs:

7.5.1 Anatomical Models

7.5.2 Surgical Positioning Templates / Guides

7.5.3 Osteotomy Templates / Guides

7.5.4 Plate Bending Templates / Guides

7.5.5 Patient Specific Case Reports

7.6 The VSP® System also contains Stainless Steel Cutting and Drill Inserts (VSP® System Accessories) which are intended to be used by the physician to guide cutting and drilling activities during the surgical procedure. The inserts fit into a standard slot / hole in the cutting / drill guides, and can be used across all VSP® System guides and templates.

8 COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

8.1 The intended use and technological characteristics of the subject device (modified VSP® System) are either identical or substantially equivalent to the predicate device (unmodified VSP® System). The potential impact on substantial equivalence of each technological difference was addressed by extensive risk analysis and verification and validation testing.

8.1.1 The modified VSP® System employs similar fundamental technologies as the unmodified version of the device:

8.1.1.1 Software for image transfer, manipulation, and surgical planning;

8.1.1.2 Hardware for rapid manufacturing of patient-specific anatomical models, guides and templates

8.1.2 The principles of operation and technological characteristics are all either identical or substantially equivalent between the modified and unmodified VSP® System.

8.1.3 The modified VSP® has the following identical technological characteristics:

8.1.3.1 System Inputs: Images from medical scanners (i.e. CT) or standard implant files (.STL format)

8.1.3.2 System Outputs: Physical and digital outputs such as patient-specific anatomical models, cutting and drill guides, templates and splints

8.1.3.3 Materials: Biocompatible polymers and surgical instrument grade stainless steel

8.1.3.4 Sterility Assurance Level: 1×10^{-6}

8.1.4 The modification that prompted the submission of this Special 510(k) is the addition of patient contoured implant files from the implant vendor to the list of cleared system inputs. The unmodified VSP® System was cleared to use standard (non-bent) implant files from the implant vendor for manipulation into patient-specific digital and / or physical implant templates. Both the standard and the patient contoured implant files are in .STL format, are used by the system to create patient-specific digital and / or physical implant

templates, and have pre-determined fixation holes to assist the surgeon in implant fixation.

8.1.4.1 See subsection 9 below for a description of the performance testing and the results that support a determination of substantial equivalence.

8.1.5 The intended use of the modified VSP® System has not been modified in any way since the clearance of the unmodified VSP® System:

8.1.5.1 Both devices are intended to provide tools and accessories (software for image manipulation, anatomical models, guides and templates) for use in reconstructive or orthognathic surgery.

8.1.5.2 The modified VSP® System and its 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.

8.1.5.3 The modified and unmodified VSP® Systems are both intended for use on surgical candidates undergoing complex reconstructive or orthognathic surgery.

8.1.6 The modified and unmodified VSP® System Accessories are manufactured to ASTM F899-11 and are sterilized by the healthcare facility with the same cycle as the other cleared system outputs. The addition of the 2.0mm drill guide to the modified VSP® System Accessories does not change the intended use of the system or of the VSP® System Accessories; therefore, a determination of substantial equivalence between the modified VSP® System and the unmodified VSP® System can be made.

9 SUMMARY OF PERFORMANCE TESTING

9.1 Verification and validation testing was performed on the modified VSP® System as a part of the Medical Modeling Design Control Program. The intention of these tests was to provide objective evidence that the modified VSP® System conforms to specifications, is fit for its intended use, and that its performance is substantially equivalent to the unmodified VSP® System.

9.2 Because the modified VSP® System is the combination of a manufacturing process and the patient-specific outputs of the manufacturing process (models, guides and templates), the performance testing for the device typically includes methods of process validation (IQ, OQ, PQ). Due to the specific nature of the device modification that was subjected to system validation, it was determined that successful execution of the validation would comprise the following challenge: 1) use as input a worst-case patient contoured implant file, 2) process the worst-case patient contoured implant file using currently validated software versions, and 3) output digital files for templates and guides that meet requirements.

9.3 The final output .STL files the cases designed using a patient contoured implant .STL file as input demonstrated clinical and / or dimensional equivalency to .STL files produced using a standard implant .STL file as input. The equivalency was demonstrated through surgeon approval by a reconstructive surgeon, and / or successful dimensional overlay of parts for comparison analysis. The reconstructive

surgeon approved both design, which indicated that there is no clinically significant difference between the implant template .STL file created from a patient contoured implant .STL file and a standard implant .STL file.

9.4 Additional Verification and Validation Testing

9.4.1 Medical Modeling has also implemented minor modifications to the device since the original clearance in K120956, which required additional verification and validation testing. A summary of these modifications and their associated verification and validation is provided below.

9.4.1.1 Software Updates: Four (4) software components were upgraded to match the vendor's current version of the software component. The following tests were executed for each software version upgrade:

9.4.1.1.1 Software installation qualification

9.4.1.1.2 Software validation

9.4.1.2 Additional Stereolithography Apparatus (SLA): An additional SLA model and associated wash tanks have been added to the manufacturing process of the VSP® System, in order to manage a larger capacity of outputs. The operational software for the additional SLAs have been incorporated into the VSP® as a result. The following verification and validation was performed for these modifications:

9.4.1.2.1 Installation Qualification (IQ)

9.4.1.2.2 Operational Qualification (OQ)

9.4.1.2.3 Performance Qualification (PQ)

9.4.1.2.4 Software Validation

9.5 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 were established in order to demonstrate device performance and substantial equivalence of the system to the unmodified version of the device.

10 SUBSTANTIAL EQUIVALENCE

10.1 Based on a comparison of the intended use and technological characteristics, the modified VSP® System is substantially equivalent to the identified predicate device. Minor differences in technological characteristics were demonstrated by performance data to have no effect on substantial equivalence and validation data supports that they system performs in accordance with its intended use and is substantially equivalent to the following predicate device:

10.1.1 VSP® System, Medical Modeling Inc., (K120956)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 22, 2014

Medical Modeling Incorporated
C/O Mr. Jonathan Kahan
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K133907
Trade/Device Name: VSP® System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZJ, LLZ
Dated: December 23, 2013
Received: December 23, 2013

Dear Mr. Kahan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Kwame O. Ulmer
-S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133907

Device Name
VSP(R) System

Indications for Use *(Describe)*
The Medical Modeling VSP(R) 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(R) 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(R) 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary S. Runner -S
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