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

September 23, 2016

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

Re: K151285
Trade/Device Name: VSP Cranial System
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: PPT
Dated: September 21, 2016
Received: September 22, 2016

Dear Ms. 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. 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151285

Device Name
VSP Cranial System

Indications for Use *(Describe)*
The 3D Systems, Inc. VSP Cranial System is intended for use as a collection of software to provide image segmentation and transfer of imaging information from a CT based medical scanner. The input data file is processed by the VSP Cranial System and the result is an output data file that may then be provided as digital models or used as input in the production of physical outputs including anatomical models, templates, and surgical guides for use in the marking or cutting of cranial bone in cranial surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

1. INTRODUCTION

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

2. APPLICANT NAME AND ADDRESS

Name: 3D Systems, Inc.

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: September 23, 2016

3. DEVICE NAME AND CLASSIFICATION

Trade Name: VSP® Cranial System

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

Classification Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories

Classification: Class II, 21 CFR 882.4310

Product Code: PPT

4. PREDICATE DEVICE

- VSP® System, 3D Systems (K133907)

5. DESCRIPTION OF THE DEVICE

The 3D Systems VSP® Cranial System is a collection of Commercial Off-The-Shelf (COTS) software, third party medical device software, and custom software intended to provide a variety of outputs to support cranial reconstructive surgery. The system uses CT based imaging data 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, and patient specific case reports.

3D Systems employees utilize a combination of Commercial Off-The-Shelf (COTS) software, third party medical device software, and custom software to manipulate CT based imaging data 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 3D Systems 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.

The VSP® Cranial System is made up of 10 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 cranial region.

The VSP® Cranial System requires an input 3D image file from CT based imaging systems. 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.

System Outputs:

- Anatomical Models
- Surgical Positioning Templates / Guides
- Osteotomy Templates / Guides
- Patient Specific Case Reports

The VSP® Cranial System also contains Stainless Steel Cutting and Drill Inserts (VSP® Cranial 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® Cranial System guides and templates.

6. INDICATIONS FOR USE

The 3D Systems, Inc. VSP® Cranial System is intended for use as a collection of software to provide image segmentation and transfer of imaging information from a CT based medical scanner. The input data file is processed by the VSP® Cranial System and the result is an output data file that may then be provided as digital models or used as input in the production of physical outputs including anatomical models, templates, and surgical guides for use in the marking or cutting of cranial bone in cranial surgery.

The Indications for Use statement for the VSP® Cranial System is nearly identical to the predicate device, differing only in anatomical region. The anatomical region for which the predicate device is

intended is listed as maxillofacial, indicating that the device may be used only for maxillofacial applications. The VSP® Cranial System is specific to only the cranial region, and excludes maxillofacial applications. The change in anatomical region presented in the Indications for Use statement of the VSP® Cranial System as compared to the predicate device do not change the therapeutic effects of the device.

Both the subject and predicate devices have the same intended use for providing image segmentation for the transfer of imaging information from a medical scanner, pre-operative software tools for simulating / evaluating surgical treatment options, and patient specific outputs for use in reconstructive surgery.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use and technological characteristics of the subject device (VSP® Cranial System) are either identical or substantially equivalent to the predicate device (VSP® System), differing only in the anatomical region for which they are intended. The potential impact on substantial equivalence of each technological difference was addressed by extensive risk analysis and verification and validation testing.

The VSP® Cranial System employs identical fundamental technologies as the predicate device:

- The VSP Cranial System uses a subset of the software previously cleared in the predicate device.
- Hardware for rapid manufacturing of patient-specific anatomical models, guides and templates is identical to the previously cleared predicate device.

The principles of operation and technological characteristics are all either identical or substantially equivalent between the VSP® Cranial System and the predicate device.

The VSP® Cranial System has the following identical technological characteristics:

- System Inputs: Images from CT based medical scanners
- System Outputs: Physical and digital outputs such as patient-specific anatomical models, cutting and drill guides, and templates
- Materials: Biocompatible polymers and surgical instrument grade stainless steel
- Sterility Assurance Level: 1 x 10-6

The intended use of the VSP® Cranial System is similar to the predicate device, differing only in the anatomical region in which the device is intended for:

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

- The VSP® Cranial 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.
- The VSP® Cranial System and its predicate device are both intended for use on surgical candidates undergoing complex reconstructive surgery.

The VSP® Cranial System and its predicate's accessories are manufactured to ASTM F899-11 and are sterilized by the healthcare facility with the same cycle as the other system outputs.

8. SUMMARY OF PERFORMANCE TESTING

The planning/design process, materials, manufacturing process, cleaning methods and sterilization methods for VSP® Cranial System are identical to those used for the predicate device. Therefore, the following testing was leveraged from the predicate device:

- Biocompatibility testing
- Cleaning and sterilization testing
- Software verification and validation testing
- Performance testing
  - Process validation (IQ/OQ/PQ)
  - Simulated Use (Planning session)
  - Mechanical testing

VSP® Cranial System output guides and templates differ from the predicate device only in size and shape to accommodate the anatomical region for which they are intended. To address any concerns with the similar performance of the VSP® Cranial System, the following performance data were provided in addition to the leveraged testing to support the substantial equivalence determination:

Test	Test Method Summary	Results
Packaging Validation	Product packaging and labels were tested according to ASTM D4577, ASTM D642, Method A, ASTM D4728, ASTM D3580, ASTM D5276, ASTM D6179, ASTM D880, ASTM D6179, ASTM D6653, and National Motor Freight Classification Rule 180	All packaging and labeling met the required acceptance criteria
Sterilization Compatibility	To ensure VSP® Cranial System outputs are compatible with the validated sterilization method, outputs were subjected to a single sterilization cycle and visually/dimensionally inspected	All acceptance criteria was met

Test	Test Method Summary	Results
Dimensional Analysis	Sizes and shapes of VSP® Cranial System templates and guides were selected to challenge the system and were dimensionally inspected to verify conformance to the product requirements	All acceptance criteria was met
Bioburden	Bioburden testing was conducted on VSP® Cranial System templates, guides, anatomical models, and metal accessories per ISO 11737-1, USP <61> and USP <1227>	All acceptance criteria was met
Pyrogenicity testing	Pyrogenicity testing was conducted on VSP® Cranial System templates, guides, anatomical models, and metal accessories per AAMI ST72, USP <85>, and USP <161>	All samples met the acceptance criteria of ≤ 2.15 EU/device

Summary

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

Based on a comparison of the intended use and technological characteristics, the VSP® Cranial System is substantially equivalent to the identified predicate device. Minor differences in the indications for use do not raise new or different questions of safety and effectiveness. Validation data supports that the system performs in accordance with its intended use and is substantially equivalent to the predicate device.