August 11, 2022

VHA DEAN
℅ Laura Gilmour
Principal Consultant
LG Strategies, LLC
2001 Parker Lane #122
Austin, Texas 78741

Re: K220648
Trade/Device Name: OMF ASP System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: June 8, 2022
Received: July 11, 2022

Dear Laura Gilmour:

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 E. Adjodha, M.ChE.
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)*
K220648

Device Name
OMF ASP System

Indications for Use *(Describe)*
The OMF ASP 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 OMF ASP System, and the result is an output data file that may then be provided as digital models or used as input to an additive manufacturing portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The OMF ASP 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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5. 510(k) Summary

5.1 Applicant/Submitter

Company Name	VHA DEAN
Company Street Address	810 Vermont Avenue, NW
City	Washington
State	DC
Country	United States
Zip Code	20420

5.2 Contact Person

Full Name	Beth Ripley, MD, PhD
Job Title	Deputy Chief
Email	beth.ripley@va.gov

5.3 Correspondent Information

Full Name	Laura Gilmour
Job Title	Principal Consultant, Advanced Manufacturing and Regulatory Strategy
Phone	901-258-3629
Email	laura.gilmour@va.org

5.4 Date of Preparation

Date of Preparation	August 10, 2022

5.5 Device Information

Table 5.1 Device Information

Trade Name	OMF ASP System
Common or Usual Name	Patient specific maxillofacial anatomical models, templates, guides, and surgical plans
Classification Name	Bone cutting Instruments and Accessories. System, Image Processing, Radiological
Classification Regulation	872.4120
Regulatory Class	Class II
Product Code	DZJ
Subsequent Product Code	LLZ

5.6 Predicate Device(s)

Table 5.2 Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer
Primary Device	K192192	VSP 2.0 System	3D Systems

The predicate devices have not been subject to a design-related recall.

5.7 Device Description

The Oromaxillofacial Advanced Surgical Planning (OMF ASP) System utilizes Commercial Off-the-Shelf (COTS) software to manipulate 3D medical images (CT-based systems) with surgeon input, and to produce digital and physical patient specific outputs including surgical plans, anatomic models, templates, and surgical guides for planning and performing maxillofacial surgeries.

The system utilizes medical imaging, such as CT-based imaging data of the patient's anatomy to create surgical plans with input from the physician to inform surgical decisions and guide the surgical procedure. The system produces a variety of patient specific outputs specific to the maxillofacial region including anatomic models (physical and digital), physical surgical templates and/or guides, and patient specific case reports. The system utilizes additive manufacturing to create patient specific guides, templates, and anatomical models.

The following table provides a list of OMF ASP System outputs by material and function:

Category	Material	Function
Marking Guide	Duraform ProX PA	• Marking of maxillofacial bone • Marking of graft bone
Positioning Guide	Duraform ProX PA	• Positioning of maxillofacial bone
Template/ Anatomical Model	Duraform ProX PA	• Visualization and fit check of graft anatomy • Visualization of anatomy at time of medical scan • Visualization of patient specific anatomy modified by established surgical plan

5.8 Intended Use/Indications for Use

The OMF ASP 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 OMF ASP System, and the result is an output data file that may then be provided as digital models or used as input to an additive manufacturing portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The OMF ASP System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

5.9 Comparison of Technological Characteristics with Predicate

VHA DEAN believes that the OMF ASP System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar inputs and outputs as the devices cleared in K192192. The subject device uses an identical material to a subset of the devices cleared in K192192. The subject device has the same intended use and similar technological characteristics to the devices cleared in K192192. These technological characteristics include image transfer and manipulation via COTS software that is later used for 3D printing of anatomical models and guides for surgical planning. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

5.10 Summary of Non-Clinical Testing

The following tests were performed to demonstrate safety based on current industry standards:

5.10.1 Design Validation

Design validation was performed to ensure OMF ASP System guide designs conform to user needs and intended use of supporting maxillofacial surgeries. The OMF ASP System has identical indications for use, identical design envelope, and an identical worst-case configuration and post processing conditions to the predicate device. All acceptance criteria for design validation were met.

5.10.2 Performance Testing

Process performance testing was completed to assess the manufacturing process as well as operator repeatability within the digital workflow. Cases used for testing were representative of the reconstruction procedures within the subject device's intended use. Both digital and physical outputs from all manufacturing processes were verified against the design specifications. All acceptance criteria for performance testing were met.

5.10.3 Software Verification

No custom software has been created or included as part of the subject device. All software used in the OMF ASP System process is commercial off-the-shelf (COTS) software. The software verification complied with two FDA guidance documents: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* issued May 11, 2005 and *Off-The-Shelf Software Use in Medical Devices Guidance for Industry and Food and Drug Administration Staff* issued September 9th 2019. Software documentation and software verification were completed to comply with a Moderate Level of Concern for the subject device as described in the aforementioned guidance documents. All acceptance criteria for software verification testing were met.

5.10.4 Cleaning and Sterilization Validation

The OMF ASP System has identical indications for use, identical design envelope, and an identical worst-case configuration and post processing conditions to the predicate device.

Cleaning validation was performed in accordance with AAMI TIR 30. Following soiling and cleaning of the subject devices, bioburden, protein levels, and hemoglobin levels were analyzed. All acceptance criteria for the cleaning validation were met.

Steam sterilization validations were performed for dynamic-air-removal cycle in accordance with ISO 17665-1 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. All acceptance criteria for the steam sterilization validation were met.

5.10.5 Biocompatibility Testing

The OMF ASP System has identical indications for use, identical design envelope, and an identical worst-case configuration and post processing conditions to the predicate device. All acceptance criteria for biocompatibility were met and the testing adequality addresses biocompatibility for the output devices and their intended use. Biocompatibility testing was in compliance to *ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, ISO 10993-5 Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization, and ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity.*

5.11 Clinical Testing

No clinical data were provided in order to demonstrate substantial equivalence.

5.12 Conclusion

Based on the testing performed, including, design validation analysis, performance testing, software verification, biocompatibility testing, cleaning validation, and sterilization validation it can be concluded that the subject device does not raise any new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed OMF ASP System are assessed to be substantially equivalent to the predicate device.