June 9, 2020

ImmersiveTouch
P. Pat Banerjee
CEO
708 Kristin Court
Westmont, Illinois 60559

Re: K181813
Trade/Device Name: ImmersiveView Surgical Plan (IVSP®)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: May 8, 2020
Received: May 13, 2020

Dear P. Pat Banerjee:

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)*
K181813

Device Name
ImmersiveView Surgical Plan (IVSP®)

Indications for Use *(Describe)*
ImmersiveView Surgical Plan (IVSP®) is intended for use as a software system for the the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the ImmersiveView Surgical Plan (IVSP®) 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, surgical splints, and surgical guides for use in maxillofacial surgery. The ImmersiveView Surgical Plan (IVSP®) 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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510(K) Summary – K181813

Submitter

Name: ImmersiveTouch, Inc.

Address: 910 West Van Buren, Suite 715, Chicago, IL 60607 US

Contact Person: Dr. P. Pat Banerjee

Date Prepared: June 8th , 2020

Name of Device and Classification Name

Device Name: ImmersiveView Surgical Plan (IVSP®)

Regulation Name: Bone Cutting Instrument and Accessories

Regulation Number: 872.4120

Product Code: Primary – DZJ; Secondary – LLZ

Classification Panel: Dental

Predicate Device

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

Indications for Use

ImmersiveView Surgical Plan (IVSP®) 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 ImmersiveView Surgical Plan (IVSP®) 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, surgical splints, and surgical guides for use in maxillofacial surgery. The ImmersiveView Surgical Plan (IVSP®) system is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

Device Description

The ImmersiveView Surgical Plan (IVSP®) system is a software based pre-surgical planning system. It is intended for use as a software system for the transfer of imaging information from a medical scanner such as CT based system. Physical outputs include surgical splints, and surgical guides that will be used in maxillofacial surgery. Surgical marking guides and surgical splints are not intended to come in contact with surgical cutting or drilling tools and therefore should not interface with surgical cutting or drilling tools.

ImmersiveTouch receives patient specific medical imaging information which is further utilized by ImmersiveTouch trained employees within the ImmersiveView Surgical Plan (IVSP®) system. This includes software to extract anatomical areas of interest from 3D medical scan images and create patient-specific physical and digital outputs. Throughout the process, a physician reviews and approves the plan prior to delivery of the final outputs.

Physical model outputs include surgical splints, and surgical guides for use in maxillofacial surgery. Surgical splints and surgical guides are designed and manufactured by ImmersiveTouch trained employees. Trained employees utilize the ImmersiveTouch additive manufacturing workflow to design and manufacture surgical guides, and, surgical splints using polymer resin. Surgical splints and surgical guides are provided in a NON-sterile condition and instructions for use provide the steps for cleaning and sterilization prior to use in surgery. Surgical splints and surgical guides are manufactured based on recommendations outlined in the FDA Guidance Document "Technical Considerations for Additive Manufactured Medical Devices."

Prior to use in surgery, the physician confirms the accuracy and level of precision by attaching surgical splints and surgical guides to the anatomical models. Anatomical models are designed and manufactured using similar workflow and materials as the subject devices.

Reports are generated for each patient specific case illustrating the plan and accompany the physical outputs that are delivered once verified and approved by the physician.

Performance Data

The performance data indicates that the verification and validation testing performed on the ImmersiveView Surgical Plan (IVSP®) system successfully demonstrates that design outputs meet design inputs.

Device Performance Validation

The performance testing for the device includes processes validation methods such as IQ, OQ, and PQ to ensure that the manufacturing process can effectively produce patient matched devices. Equipment used for production purposes have been qualified to ensure the equipment used for manufacturing of surgical guides, surgical splints and, anatomical models

meet production needs. Surgical splints, and surgical guides are manufactured based on recommendations outlined in the FDA Guidance Document “Technical Considerations for Additive Manufactured Medical Devices.”

Sterilization Validation

Sterilization validation was conducted in accordance with international standard ISO 17665 and FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." to a sterility Assurance Level (SAL) of $1x10^{-6}$. All test method acceptance criteria were met.

Biocompatibility Validation

Biocompatibility validation was conducted in accordance with international standard ISO 10993-1 and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The results of the testing adequately address biocompatibility for the output devices and their intended use.

Mechanical Strength Testing

The subject device was tested for flexural deformation testing. The result of the testing concluded that subject device was in accordance with the pre-defined acceptance criteria.

Substantial Equivalence

ImmersiveView Surgical Plan (IVSP®) is substantially equivalent to the identified predicate based on indications for use, principles of operation, technological characteristics, inputs, and outputs. Minor differences in the surgical planning and manufacturing processes are verified and validated in the performance data in accordance with the intended use.

The input is medical scanner images such as CT and CBCT. Outputs are physical and digital that include surgical splints and surgical guides.
Biocompatible materials are used in the creation of the subject devices.

All devices are intended to aid in maxillofacial surgeries. These systems are intended to be utilized by trained employees with the approval by the physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
	IVSP® System, Immersive Touch, Inc.	**VSP® System Medical Modeling Inc.**
510(k) Number	K181813	K120956
Clearance Date	TBD	12/12/2012
Computer	PC Workstation	PC workstation
Image Sources	CT	CT
Indications for Use	ImmersiveView Surgical Plan (IVSP®) 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 ImmersiveView Surgical Plan (IVSP®) 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, surgical splints, and surgical guides for use in maxillofacial surgery. The ImmersiveView Surgical Plan (IVSP®) system is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	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
Preoperative software	Yes	Yes
Human Intervention for Interpretation of images	Yes	Yes
Additive manufacturing of patient specific surgical splints, surgical guides and anatomical models	Yes	Yes
Data inputs	Images from medical scanners	Images from medical scanners
Data outputs	Output for surgical splints, surgical guides and anatomical models	Output for anatomical models, templates, and surgical guides
Physical Outputs	Surgical splints, surgical guides, and anatomical models	Anatomical models, templates, and surgical guides
Materials	Biocompatible polymers	Biocompatible polymers and surgical stainless steel
Sterilization	Subject device is provided NON-sterile and is sterilized by the end-user	Same

Comparison of Technological Characteristics with the Predicate Device

ImmersiveView Surgical Plan (IVSP®) system is substantially equivalent to and it is as safe and effective as its predicate device (VSP® System, Medical Modeling, Inc. -K120956).

Similarities to Predicate

The ImmersiveView Surgical Plan (IVSP®) and VSP® systems utilizes similar technologies as identified by its predicate device including:

- Software for image transfer, manipulation, and surgical planning. These differences in software were addressed via verification and validation testing of the system.
- Hardware for additive manufacturing of patient specific surgical splints, surgical guides, and anatomical models. These differences in software were addressed via verification and validation testing of the system

ImmersiveView Surgical Plan (IVSP®) and VSP® systems have similar technological characteristics including:

- System inputs: Images from medical scanners
- System Outputs: Physical outputs such as patient specific surgical splints, surgical guides, and anatomical models.
- Software: The subject and predicate devices both use similar software components for the digital workflow. Difference in the software used were addressed via verification and validation testing of the system.
- Materials: Biocompatible polymers
- Sterility Assurance Level: $1x10^{-6}$

The intended use of ImmersiveView Surgical Plan (IVSP®) system and its predicate device is substantially equivalent in the following respect:

- ImmersiveView Surgical Plan (IVSP®) system and the identified predicate device are intended to be used by trained personnel with active support from the surgeon. ImmersiveView Surgical Plan (IVSP®) system and the identified predicate device are intended for use on surgical candidates undergoing maxillofacial surgeries.

Differences to Predicate

The following technological differences exist between the subject and predicate device:

- The subject device does not include surgical stainless-steel inserts because the subject devices are not intended to come in contact with surgical cutting or drilling tools.
- The indications for use statements differ slightly in that the predicate device lists the physical outputs to include “anatomical models, templates, and surgical guides”

whereas the subject device includes “anatomical models, surgical guides, and surgical splints” The predicate device includes surgical splints in the device description, but surgical splints were included in the indications for use of the subject device to describe all physical outputs..

- The subject and predicate device both use biocompatible polymers to manufacture system outputs, but the materials used by the predicate device is different from the material used by the subject device.
- The workflow that both the subject device and predicate device use is different. In order to address the differences IQ, OQ, and PQ testing was conducted along with verification and validation activities.

Conclusion

ImmersiveView Surgical Plan (IVSP®) is substantially equivalent to and is as safe and effective as its predicate device. Both devices incorporate similar inputs, operations, and outputs.