ImmersiveTouch, Inc.
% P. Pat Banerjee, Ph.D.
CEO
910 W. Van Buren St, Suite 715
CHICAGO IL 60607

September 29, 2021

Re: K210726
Trade/Device Name: ImmersiveTouch
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 20, 2021
Received: August 24, 2021

Dear Dr. 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K210726

Device Name
ImmersiveTouch

Indications for Use *(Describe)*
ImmersiveTouch is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. ImmersiveTouch is also intended for measuring and treatment planning. ImmersiveTouch output can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replicas generated from digital output files are not for diagnostic purpose.

ImmersiveTouch should be used in conjunction with expert clinical judgment.

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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I M M E R S I V E T O U C H, I N C

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510K Summary K210726

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Contact Person: Dr. P. Pat Banerjee

Date Prepared: September 27th, 2021

Name of Device and Classification Name

Device Name:	ImmersiveTouch
Regulation Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulation Class:	Class II
Product Code:	LLZ

Predicate Device

ImmersiveTouch is claimed to be substantially equivalent to Mimics Medical (K183105).

Device Name:	Mimics Medical
Regulation Name:	Picture archiving and communications system
Regulation Number:	21 CFR 892.2050
Regulation Class:	Class II
Product Code:	LLZ

Indications for Use

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Device Description

ImmersiveTouch is a stand-alone modular software package that allows user to import, visualize and segment medical images to create accurate 3D representations. The 3D models can be utilized in ImmersiveTouch for measuring, treatment planning and generating and output file to be further used as an input for additive manufacturing.
This modular package includes, but is not limited to the following functions:

* Importing medical images in DICOM format for visualization, segmentation, and analysis.
* Viewing of medical imaging data in the axial. coronal and sagittal views.
* Calculating a digital 3D model and editing the model.
* Measurements on 3D models.
* Treatment Planning on 3D models with cutting planes and the ability to move cut objects.
* File export for 3D Printing.

Comparison of Technological Characteristics with the Predicate Device

The ImmersiveTouch software employs similar fundamental technologies as the identified predicate devices, including:

* The subject and predicate device share similar image segmentation functionalities.
* The subject and predicate device both have similar abilities to process, review and analyze medical imaging data
* The subject and predicate device both generate an output file

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

* The inputs to the subject device are equivalent to a subset of the inputs of the predicate device.
* The outputs to the subject device are equivalent to a subset of the outputs of the predicate device.

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Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
This includes verification against defined requirements, and validation against user needs. Both end-user validation and bench testing were performed.
Software verification and validation includes:

* Verification of each independent software subsystem against defined requirements.
* Verification of interfaces between software subsystems against defined requirements.
* Validation of fully integrated systems including all subsystems against overall system requirements.

Measurements Study
The purpose of the study was to evaluate, measure and compare the inter and intra user variability between measurements taken by multiple users in the subject device. Comparison of the inter and intra user measurements showed that all measurements fell within the set acceptance criteria.

Segmentation Study
The purpose of the study was to visually compare segmentation models created by both the subject and predicate devices. The results were validated by subject matter experts. The comparison showed similarity in all models.

Output Study
The purpose of the study was to evaluate, measure and compare the exported models that were created using the subject and predicate device from a CT scan. Comparison between the exported models of both software systems revealed that all measurements fell within the set acceptance criteria.

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Summary

The performance data indicates that the verification and validation testing performed on ImmersiveTouch software successfully demonstrates conformity to pre-established specifications and acceptance criteria. The acceptance criteria were established to demonstrate device performance and substantial equivalence of the software to the predicate device.

Conclusions

ImmersiveTouch is substantially equivalent to and is as safe and effective as its predicate device. Both devices incorporate similar inputs, operations, and outputs.