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

Immersive Touch, Inc.
% Prashant Banerjee, Ph.D.
President
708 Kristin Court
WESTMONT IL 60559

December 16, 2014

Re: K140860
Trade/Device Name: ImmersiveTouch3 and MicrovisTouch
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 17, 2014
Received: November 21, 2014

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. 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,

Robert A Ochs

Robert A. Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K140860

Device Name
ImmersiveTouch3
MicrovisTouch

Indications for Use *(Describe)*
The ImmersiveTouch simulators are intended as pre-operative software for simulating and 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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510K Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

ImmersiveTouch, Inc.
708 Kristin Court
Westmont, Illinois 60559
Phone # 1-630-570-5943

Contact Person:

P. Pat Banerjee
CEO
ImmersiveTouch
Date Prepared: August 12th, 2014

Name of Device and Classification Name.

Device Name: ImmersiveTouch3
Device Name: MicrovisTouch
Regulation Name: Picture archiving and communications system
Regulation Number: 892.2050
Product Code: LLZ
Classification Panel: Radiology

Predicate Device

Surgical Theater Surgery Rehearsal Platform (K123023)
Simbionix PROcedure Rehearsal Studio (K112387)

Intended Use

The ImmersiveTouch simulators are intended as pre-operative software for simulating and evaluating surgical treatment options.

Technological Characteristics and Substantial Equivalence

A. Device Description

The ImmersiveTouch is software based pre-surgical planning system. It is intended for use as a software interface. It is also intended as pre-operative software for simulation and evaluation of surgical treatment options.

The ImmersiveTouch software has the capability of displaying 3D models of patient data from 2D scan slices. Additionally, it provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.

The 3D models of patient data are combined with the use of haptics. This provides the user with ability to modify the haptic properties, creating the sensation of feeling specific tissues.

B. Substantial Equivalence

The ImmersiveTouch is substantially equivalent to the Surgery Rehearsal Platform (K123023) and Simbionix PROcedure Rehearsal Studio (K112387). The ImmersiveTouch is substantially equivalent to its predicate devices in that it uses a PC workstation that allows for the viewing of CT and MRI images. These images can be used in pre-operative software for simulating and evaluating surgical treatment options.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS			
Characteristic	**ImmersiveTouch**	**Surgery Rehearsal Platform**	**Simbionix PROcedure**
510(k) Accession Number	K140860	K123023	K112387
Clearance Date	TBD	2/8/2013	12/27/2011
Computer	PC Workstation	Same	Same
Image Sources	CT and MRI	Same	Same
Indications for Use	The ImmersiveTouch simulators are intended as pre-operative software for simulating and evaluating surgical treatment options.	Software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to output file. Intended as pre-operative software for simulating and evaluating surgical treatment options	Same as Surgery Rehearsal Platform
Patient Contact	No	No	No

C. Performance Data

The ImmersiveTouch has been successfully tested, verified and validated to ensure that it meets specifications. The ImmersiveTouch was CE certified by Underwriters Laboratories under the standard IEC 60950-1:2005 (2nd Edition); Am 1:2009.

The ImmersiveTouch has also been tested in accordance with IEC 60601-1 and IEC 60601-1-2 standards.

D. Conclusions

ImmersiveTouch, Inc. believes the ImmersiveTouch is substantially equivalent to and is as safe and effective as its predicate devices. While they have different indications for use, all devices are constructed from similar materials and incorporate similar operational principles. Results of performance tests conducted on the pre-operative software clearly demonstrate the device is safe and effective for its intended use.