ImmersiveTouch
Prashant Banerjee
CEO
910 W Van Buren Street, Suite # 715
CHICAGO, ILLINOIS 60607

October 16, 2023

Re: K230249
Trade/Device Name: Ikshana
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 11, 2023
Received: September 14, 2023

Dear Prashant 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230249

Device Name
Ikshana

Indications for Use *(Describe)*
Ikshana is a software device to display medical images. It includes functions for image review, image manipulation, measurements, and 3D visualization.

Medical images may only be interpreted using an FDA-cleared display monitor that meets technical specifications that are reviewed and accepted by the FDA.

Ikshana is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. Display monitors used for reading medical images for diagnostic purposes must be FDA-approved radiology monitors.

Ikshana software is indicated for use by qualified healthcare professionals, including, but not restricted to, radiologists, non-radiology specialists, physicians, and technologists.

When accessing the Ikshana software from a wireless stereoscopic head-mounted display (HMD) or mobile device, the images viewed are for informational purposes only and are not intended for diagnostic use.

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.

510(k) Summary

I. SUBMITTER

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Contact Person: Dr. P. Pat Banerjee
Date Prepared: January 15th, 2023

II. DEVICE

Device Name: Ikshana
Regulation Name: Medical Image Management and Processing System
Regulation Number: 21 CFR 892.2050
Regulation Class: II
Product Code: LLZ

III. PREDICATE DEVICE

Ikshana is claimed to be substantially equivalent to predicate device SurgicalAR (K190764).

Ikshana is also substantially equivalent to reference device Mimics Medical (K183105) in its ability to perform image segmentation based on input data.

IV. DEVICE DESCRIPTION

Ikshana is a stand-alone modular software platform to be used by clinicians for the visualization of medical images in 3D to allow for surgical planning activities. The device takes 2D medical images and creates accurate 3D representations that clinicians can then view on a stereoscopic display. This modular package is used to

- Load patient CT/MR DICOM data
- View DICOM data using a traditional computer monitor or in Augmented Reality (AR) using a head-mounted display, HMD (Microsoft HoloLens 2).

HoloLens 2 Specifications

S. No.	Specifications	HoloLens 2 (Head Mounted Display)
1	The manufacturer and model of the HMD	Manufacturer - Microsoft HMD Model - Microsoft HoloLens 2

S. No.	Specifications	HoloLens 2 (Head Mounted Display)
2	The number of horizontal and vertical pixels of the display per eye	Resolution 1440×936 per eye
3	Horizontal and vertical field of view	Given that Microsoft said the HoloLens 2 FoV has a 3:2 "screen" ratio, some basic math showed the device had a horizontal FoV of 43° and a vertical of 29°.
4	Number of pixels per degree	33 pixels per degree of field of view
5	The minimum and maximum luminance of the display	The maximum luminance of the HoloLens 2 display is reported at 500 cd/m², and the minimum luminance is 0 (for an empty pixel).
6	Unity depth buffer size	Unity depth textures at the HoloLens 2 end are 16 bits. 24-bit textures are used before images are sent to the HoloLens for the purposes of accurate pixel sorting, but this is down sampled to 16-bits before sending over the network, where it is used for latency compensation. The far planes of the virtual cameras used for rendering are set to under 10 meters, down from Unity's default value of 1000 meters, to maximize the accuracy of these depth values.
7	Maximum temperature and recommended temperature of the HMD	The devices operate in a temperature range of 10°C to 35°C.
8	HMD's interpupillary distance (IPD), the adjustment range of IPD:	The HoloLens 2 display actively color-corrects images based on the position of the user's eyes. Eye calibration provides two critical inputs: (1) the user's interpupillary distance (IPD) and (2) the direction each eye is looking. Without eye calibration, the system defaults to a nominal eye position without eye movement.
9	Eye relief and compatibility with corrective lenses	18mm to 23mm
10	Distance of the virtual content from the user in the software design	HoloLens displays are fixed at an optical distance of approximately 2.0 m away from the user. Users must always accommodate nearly 2.0 m to maintain a clear image in the device.

V. INDICATIONS FOR USE

Ikshana is a software device to display medical images. It includes functions for image review, image manipulation, measurements, and 3D visualization.

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Ikshana software is indicated for use by qualified healthcare professionals, including, but not restricted to, radiologists, non-radiology specialists, physicians, and technologists.

When accessing the Ikshana software from a wireless stereoscopic head-mounted display (HMD) or mobile device, the images viewed are for informational purposes only and are not intended for diagnostic use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

- The subject and predicate device both have the same intended use.
- The subject and predicate device both have similar abilities to process, review and analyze medical imaging data.
- The subject and predicate device both have similar functionalities to perform measurements and aid in surgical planning activities.

Differences
Ikshana can perform segmentation, which is different from the predicate listed.

Comparison with reference device of K183105 - Mimics Medical
Intended use and Functionality - Both Ikshana and Mimics Medical offer advanced image processing capabilities, including segmentation and 3D visualization. Ikshana and Mimics Medical can perform image segmentation based on the input data. However, Mimics Medical has a broader range of functionalities. Ikshana is primarily designed for 3D visualization and pre-surgical planning using diagnostic imaging systems and is not intended for primary diagnosis. In contrast, Mimics Medical encompasses a wider range of applications, including treatment planning, and the creation of output files for additive manufacturing. Ikshana specifies that medical images must be interpreted on FDA-approved radiology monitors, while Mimics Medical does not include specific display requirements in its intended use.

The results for Segmentation study have been compared with a previously cleared reference device Mimics Medical (K183105). Mimics Medical (K183105), a software interface and image segmentation system that is intended for measuring and treatment planning was used in the Performance Testing to

compare the results of the subject device. All of the results showed under this specific chapter show a high level of equivalence between Ikshana and Mimics Medical.

Features	**Description**	**Subject Device**	**Predicate Device**
		Ikshana	**SurgicalAR**
Measurement Tool	• Line • Angle	Yes	Yes
User Installation Requirements	As per IFU	Yes	Yes
Data Type Supported	• DICOM	Yes	Yes
Image View/Manipulation	• Image Zoom • Pan • Window Level • Auto Window • Reset • Image Rotate • Image Flip • Magnify/Zoom	Yes	Yes
Data Encryption	HTTPS	Yes	Yes
Patient Information Display	Capable of displaying patient information	Yes	Yes
Linking	Co-planar linking: • Auto link • Manual	Yes	Yes
User and Password Control	Yes	Yes	Yes
Data Security	Stored on server	Yes	Yes
Audit Trail	Audit trail logged	Yes	Yes
User Management	Database structure allows mapping users to group internally or mapping external groups	Yes	Yes

Features	Description	Subject Device	Predicate Device
		Ikshana	SurgicalAR
Transmission Modes	Via the web with Internet browsers	Yes	Yes
MPR Viewing	This viewing feature enables the display of reformatted CT and MR images into axial, coronal and sagittal orientations	Yes	Yes
3D Volume Rendered Viewing	This viewing feature enables the display of 3D perspective views of CT and MR image sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.	Yes	Yes
Active Target Tool	This viewing feature provides a facility to view a single target location	Yes	Yes
Crosshair Navigation and Synchronization	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time. (2D slice view)	Yes	Yes
Ability to close an image by clicking an "X" in the upper-left portion of the viewport	Ability to close an image by clicking an "X" in the upper-left portion of the viewport.	Yes	Yes
HMD support for visualization purpose only (not for diagnostic use)	This viewing feature makes Ikshana compatible with off-the shelf-wireless, Wi-Fi enabled, stereoscopic head-mounted display	Yes	Yes
Diagnostic quality medical image review	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices- via FDA approved diagnostic monitors	Yes	Yes
Image Segmentation	Ability to perform segmentation based on the input data	Yes	No
Intended Use Environment	Intraoperative use	No	No

Operator profile
Qualified healthcare professionals, including but not restricted to surgeons, radiologists, non-radiology specialists, physicians, and technologists.

Patient population
The device is software that allows for viewing of DICOM data. Therefore, this is not restricted to a specific patient population.

Operating principle
There are different operating principles such as viewing:

- On desktop PCs with a traditional monitor the interaction with the software is performed with a mouse and/or keyboard.
- On a head-mounted display, the interaction with the software is performed using hand gestures.

VII. 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 and Segmentation Study
The purpose of the Measurement 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. A combination of orthopedic, and maxillofacial models was used for this study.

For the measurement study the paired t-tests comparing Immersive Touch Ikshana measurements to Medical Mimics measurements resulted in p-values greater than 0.05, indicating a lack of significant difference between the two. Bland Altman plots also confirmed a high level of equivalence for both linear and angular measurements, with 95 percent of differences falling within acceptable limits. Overall, these findings suggested that Immersive Touch Ikshana and Medical Mimics measurements are likely equivalent.

The purpose of the Segmentation study was to visually compare segmentation models created by the subject device with a previously cleared reference device Mimics Medical (K183105). The results were validated by subject matter experts. The comparison showed a high level of equivalence between Ikshana and Mimics Medical for all the anatomical models. A combination of cardiovascular, orthopedic, and maxillofacial models was used. For the segmentation study, an average DICE

coefficient of approximately 96% was achieved for 60 trials comparing ImmersiveTouch and Materialize Mimics volumes. The paired t-test resulted in a p-value above 0.05, suggesting that the null hypothesis of no significant difference between the two volume measurements cannot be rejected, indicating likely equivalence between the two methods.

The results for Segmentation study have been compared with a previously cleared reference device Mimics Medical (K183105). Mimics Medical (K183105), a software interface and image segmentation system that is intended for measuring and treatment planning was used in the Performance Testing to compare the results of the subject device. A measurement accuracy study was conducted to analyze and validate the reproducibility and the accuracy of measurements in subject device in comparison to measurements made in Materialize Mimics. All of the results showed a high level of equivalence between Ikshana and Mimics Medical.

AR HMD Testing

The functioning of the AR HMD was tested through validation tests and the 3D anatomical representations were successfully visualized via the Head mounted display.

Summary

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

VIII. CONCLUSIONS

Ikshana demonstrates substantial equivalence to its predicate device. Both devices incorporate similar inputs, operations, and outputs.