May 14, 2021

Real View Imaging Ltd.
% Yehudit Kraizer, Ph.D.
VP Quality and Regulatory Affairs
4 Hatnufa St.
Yokneam, 2069202
ISRAEL

Re: K210072
Trade/Device Name: HOLOSCOPE-i
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 20, 2021
Received: April 20, 2021

Dear Dr. Kraizer:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210072

Device Name
HOLOSCOPE-i

Indications for Use *(Describe)*

The HOLOSCOPE-i is a medical display workstation intended for 3D image visualization and image interaction. The holograms are generated from 3D volumetric data acquired from CT and Ultrasound sources. The device is intended to provide visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the images. The HOLOSCOPE-i 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. The HOLOSCOPE-i is intended to be used as a reference display for consultation to assist the clinician who is responsible for making all final patient management decisions.

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.

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510(k) SUMMARY of K210072

Applicant Real View Imaging Ltd.

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Date Prepared January 11, 2021

Trade Name: HOLOSCOPE-i

Classification Name: System, image processing, radiological

Product Code: LLZ

Device Class: II

Regulation Number: 892.2050

Panel: Radiology

Predicate Device: K193149 - EchoPixel True 3D Viewer Software

Reference Device: K132165 - Philips QLAB Quantification (MVN) Software

Intended Use/ Indications for Use:

The HOLOSCOPE-i is a medical display workstation intended for 3D image visualization and image interaction. The holograms are generated from 3D volumetric data acquired from CT and Ultrasound sources. The device is intended to provide visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the images. The HOLOSCOPE-i 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. The HOLOSCOPE-i is intended to be used as a reference display for consultation to assist the clinician who is responsible for making all final patient management decisions.

Device Description

The HOLOSCOPE-i is a software-controlled optical system that displays 3D holographic medical images. The system generates color 3D holograms from 3D volumetric imaging datasets acquired from standard imaging modalities such as CT and 3D ultrasound.

The HOLOSCOPE-i is comprised of an Optical Unit that creates the optical path for the generation of the holographic image; a system computer and electronics supporting the

Human Machine Interactions (HMI) and a graphical user interface (GUI) display; a cart and boom mechanical fixture that mechanically connects the Optical Unit and the system computer; and a 3D Control Device for interfacing with the hologram.

Technological Characteristics / Principles of Operation

The HOLOSCOPE-i receives 3D volumetric medical imaging data from standard imaging modalities such as CT or US and generates a hologram in the holographic display. The hologram, floating in air, provides a three dimensional image of the data and enables the health care professional to visualize the image at hands reach and directly interact with the image.

The digital data required to create the hologram is imported to the HOLOSCOPE-i from a PACS, USB or directly from a connected compatible 3D Ultrasound acquisition modality. This data is the input to the Real View algorithms that run on the system computer. The output of this process is a digital interference pattern that is subsequently digitally addressed on a Spatial Light Modulator (SLM). Once coherent light is projected on the SLM optical panel, the hologram is created and guided to the desired projection area via the optical system adjacent to the SLM.

The optical system consists of two separate optical channels, one per each eye. Each optical channel consists of an SLM, a Red-Green-Blue (RGB) coherent light source, a set of lenses and mirrors to direct the light propagation ending with the see-through eyepieces that enable the viewer to see the hologram at arms-reach.

Performance Data

The following non-clinical testing was conducted to evaluate the device:

- Bench testing performance tests demonstrated the system meets its performance requirements by verifying the following elements: Resolution, sharpness, luminance response, low contrast response, contrast ratio, color representation and uniformity, 3D fidelity, object orientation and measurement accuracy.
- Electrical safety was tested in accordance with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- System cleaning and disinfection validation was performed according to AAMI TIR 30:2011/(R)2016, AAMI TIR 12:2010, and FDA guidance:" Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff" (March 17, 2015).
- The biocompatibility of all user contact materials was evaluated according to ISO 10993- 1:2018 and FDA guidance on the use of ISO 10993-1.
- Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002.

- Usability evaluation - the system was validated with intended users in simulated use conditions to ensure the user needs and intended use requirements were met. All tasks, including a critical task, were met and no new issues of safety or effectiveness were raised.

The following clinical testing was conducted to evaluate the device:

- The HOLOSCOPE-i was validated in an Expert Evaluation study. Ten adult 3DTEE and ten adult CT images each with 5 pre-identified anatomical landmarks were reviewed by expert evaluators. All landmarks were identified for all images and ease of identification, as expected, was scored at least 3, with 99% of identifications scoring 5 (very easily). There was no difference in ability to identify the structures, or the ease of identification, under both dim ambient lighting and bright ambient lighting conditions. Overall the evaluators indicated an excellent, intuitive ability to perceive the spatial relationships of the anatomical structures directly from the image, similar to “real-life” 3D depth perception supporting the intended use of the system.
- Substantial Equivalence was demonstrated in a comparative clinical study that measured features within 41 adult Mitral Valve images (19 normal, 22 pathological). The study demonstrated a high agreement in measurements, as compared to the validated reference device, similarly to comparative results previously published by the predicate. Measurements for annular diameters demonstrated very good agreement in terms of Intra-Class Correlation (ICC) between HOLOSCOPE-i and reference device (ICC 0.895; 95% CI 0.810- 0.943 and ICC 0.906; 95% CI 0.830-0.949). Very good agreement was shown for annular diameters in normal valves, as well as for pathological valves, with slightly higher agreement for pathological valves (0.864, 0.840 and 0.934, 0.943, respectively). Agreements in scallop measurements were low for both groups. Comparing the results of the True 3D Viewer to the reference device and the HOLOSCOPE-i to the reference device demonstrated similarity in the correlation for the Mitral Valve diameters and similarly low correlation for leaflet measurements. The study confirmed that that measurements of the Mitral Valve can be performed directly and accurately, within the 3D volumetric image and that the image quality of the hologram is sufficient for its intended use by enabling visualization of the measured structures and spatial understanding of the image and therefore support the substantial equivalence of the HOLOSCOPE-i to the True 3D Viewer software.

All performance testing demonstrates that the HOLOSCOPE-i performs according to specifications, as intended.

Substantial Equivalence

	Subject Device: HOLOSCOPE-i	**Predicate Device: EchoPixel True 3D Viewer Software - K193149**
Indications for Use	The HOLOSCOPE-i is a medical display workstation intended for 3D image visualization and image interaction. The holograms are generated from 3D volumetric data acquired from CT and Ultrasound sources. The device is intended to provide visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the images. The HOLOSCOPE-i is intended to be used as a reference display as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. The HOLOSCOPE-i is intended to be used for consultation to assist the clinician who is responsible for making all final patient management decisions.	The True 3D Viewer Software is intended for processing, review, analysis, communication and media interchange of digital images acquired from CT, MRI, XA and Ultrasound sources. It is also intended as software which provides visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the mentioned images. The True 3D Viewer software is designed for use by health care professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.
Intended users	Health care professional who is responsible for making all final patient management decisions.	Health care professional who is responsible for making all final patient management decisions.
Product Code	CFR 892.2050 LLZ, Radiological Image Processing Device	CFR 892.2050 LLZ, Radiological Image Processing Device
Product Class	Class II	Class II
Image type	3D stereoscopic medical hologram	3D stereoscopic medical image
Image analysis features	Interactive manipulation, zoom, rotate, move, slice, mark, measure	Interactive manipulation, tag, annotate, measure, segment
SW controlled	Yes	Yes
GUI	Yes, for users to interact with the system, select tools and drive workflow.	Yes, for users to interact with the software, select tools and drive workflow.
Device includes HW and optical elements	Optical System	3D glasses; Performance tested hardware is provided by user
Computer	PC supporting user interface SW and PC supporting system	PC; Performance tested hardware is provided by user

	Subject Device: HOLOSCOPE-i	Predicate Device: EchoPixel True 3D Viewer Software - K193149
	computations and processes, both embedded in the system.	
Display	Stereoscopic Holographic display	Stereoscopic display; Performance tested hardware is provided by user
Input image sources	CT and Ultrasound sources	CT, MRI, XA and Ultrasound sources
DICOM Compatible	Yes	Yes
Direct interaction with the image by optical motion control system	Yes	Yes. Performance tested hardware is provided by user
Visual Tracking	Yes	Yes
Original 2D/3D image remains visible (acquisition data source)	Yes	Yes

Based on the above comparison, the HOLOSCOPE-i has a similar intended use and similar technological/functional features as the predicate device in providing tools and workflow designed to support users with 3D visualization and image interaction with medical images. Similar to the cited predicate device, the HOLOSCOPE-i is used for image viewing and interaction both prior to and during procedures.

The HOLOSCOPE-i is substantially equivalent to the predicate device with regard to intended use and technological characteristics and any differences between the HOLOSCOPE-i and the predicate do not introduce different questions of safety and effectiveness. Performance testing demonstrates that the device performs as intended.