MEDIVIS, Inc.
℅ Ms. Amy Lynn
Regulatory Affairs Consultant
20 Jay Street, Suite 312
BROOKLYN NY 11201

May 13, 2019

Re: K190764
Trade/Device Name: SurgicalAR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 15, 2019
Received: March 25, 2019

Dear Ms. Lynn:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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)*
K190764

Device Name
SurgicalAR

Indications for Use *(Describe)*
SurgicalAR is a software device for display of medical images and other healthcare data. It includes functions for image review image manipulation, basic measurements and 3D visualization (MPR reconstructions and 3D volume rendering).

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

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

When accessing SurgicalAR software from a wireless stereoscopic head-mounted display (HMD) or mobile device, images viewed are for informational purposes only and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 - 510(k) Summary

K190764

Company:	MEDIVIS, Inc.
Address:	20 Jay Street, Suite 312 Brooklyn, New York, 11201
Contact:	Amy Lynn Regulatory Affairs Consultant
Telephone Number:	954.600.8299
Email:	amylynncicatello@gmail.com
Preparation Date:	March 15, 2019
Trade Name:	SurgicalAR
Device Common Name:	System, Image Processing, Radiological
Classification Regulation:	21 CFR 892.2050
Classification Name:	Picture archiving and communications system
Class:	II
Panel:	Radiology
Product Code:	LLZ
Predicate Device:	VitreaView (K163232)

5.1 Device Description

SurgicalAR is a software platform to be used by clinicians for the visualization of medical images in 3D to allow for surgical planning activities. The device takes pre-acquired 2D medical images and reconstructs 3D models that a clinician can then view on a stereoscopic, holographic display.
The software application 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.

5.2 Intended Use

SurgicalAR is a software device for display of medical images and other healthcare data. It includes functions for image review image manipulation, basic measurements and 3D visualization (MPR reconstructions and 3D volume rendering).

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

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

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

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

5.4 Patient population
The device is software which allows for viewing of DICOM data. Therefore, there is no specific patient population.

5.5 Intended use environment
The software is intended to be used:

- In operating rooms
- In office environments within hospitals or at any other location with a computer
- For informational only purposes at any location using the head-mounted display (HMD)

5.6 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 PCs with a touchscreen monitor the interaction with the software is performed with a touchscreen interface; or
- On a head-mounted display the interaction with the software is performed using hand gestures.

5.7 Part of the body or type of tissue applied or interacted with
The device is software only which allows for the viewing of DICOM data. Therefore, it does not interact with any body and/or tissue part and the viewing is also not limited to any body and/or tissue part.

5.8 Comparison to predicate device
The SurgicalAR proposed device is substantially equivalent to the predicate device, K163232, as both devices have the same intended use and technological characteristics. While both devices do not have the exact same software features, the difference does not pose any safety and/or effectiveness questions. A full substantial equivalent discussion is provided in **Section 12**. The exact feature differences and omissions are detailed in the tables contained within **Section 12**.

The proposed device slightly differs from the predicate device in two ways as listed below:

First, the proposed device is not available for use through internet browsers like the predicate device. The predicate device allows access via an internet browser in addition to traditional installation on a PC's hard drive. This design difference does not create new or additional safety risks regarding the use of the device but rather limits the scope of accessibility of SurgicalAR.

Secondly, the proposed device does not contain all of the same features as the predicate device. The lack of features are not key features nor do they impact the function or intended use of the device.

The table below demonstrates the similarities in technology and features between SurgicalAR and the predicate device.

Criteria	Description	Subject Device	Predicate Device	Comparison
		SurgicalAR	VitreaView (K163232)	
Annotation and Measurement Tools	• Line • Angle • Ruler • Arrow	Yes	Yes	Same
User Installation Requirements	• Runs within browser using HTML and JavaScript only • No installation is required on user's machine	No	Yes	Different. Predicate allows for access via Internet.
Data Type Supported	• DICOM • Non-DICOM	Yes	Yes	Same
Image View/Manipulation	• Image Zoom • Pan • Window Level •AutoWindow • Level • Reset • Scout Lines • Image Rotate • Image Flip • Magnify • Image Invert • Image Cine	No	Yes	Different. Predicate has "image invert" and "image cine" features.
Data Encryption	• HTTPS • SSL	Yes	Yes	Same

Criteria	Description	Subject Device	Predicate Device	Comparison
		SurgicalAR	VitreaView (K163232)	
Patient Demographic Display	Capable of displaying patient demographic information	Yes	Yes	Same
Linking	Co-planar linking: • Autolink • Manual	Yes	Yes	Same
User and Password Control	Users can be managed via an internal database, active directory, or parent application	Yes	Yes	Same
Data Security	Stored on server	Yes	Yes	Same
Audit Trail	Audit trail logged	Yes	Yes	Same
User Management	Database structure allows mapping users to groups internally or mapping external groups (AD, parent application) to internal groups and role			
Transmission Modes	Via the web with Internet browsers	No	Yes	Different. Predicate allows for access via Internet.
File Type Used	• JPEG for Lossy data • PNG for Lossless data	Yes	Yes	Same
MPR Viewing	This viewing feature enables the display of reformatted CT and MR images into axial, coronal and sagittal orientations	Yes	Yes	Same
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	Yes	Yes	Same

Criteria	Description	Subject Device	Predicate Device	Comparison
		SurgicalAR	VitreaView (K163232)	
	volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.			
Active Target Tool	This viewing feature provides a facility to view a single target location within multiple images.	Yes	Yes	Same
Crosshair Navigation and Synchronization	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	Yes	Yes	Same
Ability to clone images side by side	Ability to clone images side by side.	No	Yes	Different. Predicate contains a "clone" copy/paste feature.
Ability to close an image by clicking an "X" in the upper-left portion of the view port	Ability to close an image by clicking an "X" in the upper-left portion of the viewport.	Yes	Yes	Same
Ability to select locale and language settings on the login screen	Ability to select locale and language settings on the login screen.	No	Yes	Different. Predicate has support for multiple languages.
Ability to customize the columns in the study directory by selecting the dropdown arrow on	Ability to customize the columns in the study directory by selecting the dropdown arrow on the right side of each column.	No	Yes	Different. Predicate has feature to customize the view of the directory.

Criteria	Description	Subject Device	Predicate Device	Comparison
		SurgicalAR	VitreaView (K163232)	
the right side of each column.				
Help Tips	Proactive help tips appear for 10-15 seconds to educate users on certain functionality that may not be obvious to a new user.	No	Yes	Different. Predicate has feature to view "help tips".
Support for TIF Files	Vitrea View can display TIF files.	Yes	Yes	Same
Tablet support for information purpose only (Not for diagnostic use)	This viewing feature provides access of Vitrea View software on various iOS and Android tablet devices through the default internet browser. Key features are: • Two-finger pinch to zoom and pan • Touch and drag to scroll • Double-tap to access Gesture menu • Tap Carousel thumbnail, then tap Image Pane to swap images • Ambient Lighting Check	No	Yes	Different. Predicate has support for iOS and Android for non-diagnostic viewing.
HMD support for information	This viewing feature provides access of SurgicalAR software	No	Yes	Different. Proposed device has support for

Criteria	Description	Subject Device	Predicate Device	Comparison
		SurgicalAR	VitreaView (K163232)	
purpose only (not for diagnostic use)	on consumer, off-the-shelf-wireless, Wi-Fi enabled, stereoscopic head-mounted display with minimum of 2GB RAM			HMDs for non-diagnostic viewing.
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	Yes	Yes	Same

5.9 Tests conducted

Both design verification and design validation were successfully conducted as part of the testing for the SurgicalAR device.

The purpose of the design verification activity was to ensure that the design output specifications met the design input requirements. Deviations associated with the written protocol were captured within the design verification report. These deviations did not negatively impact the device, it's intended use, nor did they introduce additional risks. Therefore, it is concluded at the design verification was successful in that the design output specifications satisfactorily met the design input requirements.

Design validation, including human factors and usability engineering, was conducted. Human factors and usability engineering testing was performed to assess user interactions with the device's user interface. The purpose is to identify use errors that would or could result in serious harm to the patient or user. Human factors validation testing is also used to assess the effectiveness of risk management measures. The testing performed was simulated use. The design validation was successfully completed, and testing met all predetermined acceptance criteria. Furthermore, no additional risks to the safety or efficacy of the device were identified.

5.10 Essential performance characteristics

SurgicalAR is software for medical image visualization. A hardware shutdown, power failure or other hardware issue that makes the software inoperable does not cause harm. Therefore, no unacceptable risk arises if the hardware loses performance. The hardware does not have any essential performance characteristics. The software risks were analyzed to find risks in the intolerable range. No risks have been identified in the intolerable range. As such, no measures are considered essential performance characteristics. In summary, the SurgicalAR software does not have any essential performance characteristics.