ApoQlar GmbH
℅ Liliana Duarte
Chief Regulatory Affairs Officer
c/o the-labs.space, Raboisen 32,20095
HAMBURG, GERMANY

November 25, 2022

Re: K213215
Trade/Device Name: VSI HoloMedicine®
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 18, 2022
Received: October 19, 2022

Dear Liliana Duarte:

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,

Jessica Lamb,
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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)*
K213215

Device Name
VSI HoloMedicine®

Indications for Use *(Describe)*
VSI HoloMedicine® is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for pre-operative planning outside and/or inside the surgical room.

When accessing VSI HoloMedicine® from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. VSI HoloMedicine® is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.

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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K213215

510(k) Summary

5.1 General Information

Primary Submission Contact

Liliana Duarte

Chief Regulatory Affairs Officer
apoQlar GmbH
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Hamburg, Germany

Manufacturer / Submitter

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Hamburg, Germany

5.2 Regulatory Information

Subject Device Name	VSI HoloMedicine®
Classification Names	Medical Image Management and Processing System
Device Classification	II
Common Name	VSI HoloMedicine®
FDA Product Code	LLZ
CFR References	892.2050
Review Panel	Radiology

5.3 Identification of Predicate Device

ApoQlar regards the VSI HoloMedicine® to be substantially equivalent to the predicate K190764 the Medivis-SurgicalAR. A reference device is also used for comparison, K172418 Novarad-OpenSight.

5.4 Subject Device Description

VSI HoloMedicine is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for pre-operative planning outside and/or inside the surgical room.

When accessing VSI HoloMedicine from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. VSI HoloMedicine is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.

Indications for Use

VSI HoloMedicine is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for pre-operative planning outside and/or inside the surgical room.

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5.5 Substantial Equivalence Discussion

Any modifications between the predicate device and the subject device are provided in while the table below. The review of the indications for use and comparison characteristics provided in Table 1 demonstrate that VSI HoloMedicine® is substantially equivalent to the predicate device. A reference device was also included.

Table 1. Substantial Equivalence Discussion

Item No.	**Device Characteristic**	**Proposed Device VSI HoloMedicine®**	**Primary Predicate Device SurgicalAR K190764**	**Reference Device: Novarad- OpenSight K172418**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	**Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.**
1	510 (k) Number	K213215	K190764	K172418	N/A	Difference in 510k numbers do not impact safety or efficacy of the product.
2	Device Name, Model	VSI HoloMedicine®	SurgicalAR	OpenSight	N/A	N/A
3	Manufacturer	apoQlar GmbH	Medivis	Novarad	N/A	N/A
4	CFR Reference	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Identical	N/A
5	FDA Review Panel	Radiology	Radiology	Radiology	Identical	N/A
6	FDA Device Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	Identical	N/A
7	FDA Product Code	LLZ	LLZ	LLZ	Identical	N/A
8	Class	II	II	II	Identical	N/A

9	Indications for use	VSI HoloMedicine is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for pre-operative planning outside and/or inside the surgical room. When accessing VSI HoloMedicine from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. VSI HoloMedicine is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.	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	OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for pre-operative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation. OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the same anatomy of the patient in order to support pre-operative analysis. OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures. OpenSight is intended for use by trained healthcare professionals, including	Substantially Equivalent	N/A

			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.	surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors to better understand anatomy and pathology of patient.		
10	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	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	Healthcare settings, such as hospitals and clinics	Identical	N/A

		purposes at any location using the head-mounted display (HMD)	purposes at any location using the head-mounted display (HMD)			
11	Intended Users	Qualified healthcare professionals including surgeons, radiologists, physicians.	Qualified healthcare professionals, including but not restricted to surgeons, radiologists, nonradiology specialists, physicians, and technologists.	Qualified healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators.	Identical	N/A
12	Patient Population	The device is a software which allows for viewing of DICOM data. Therefore, its intended use is without any restrictions regarding patient population.	The device is software which allows for viewing of DICOM data. Therefore, there is no specific patient population.	OpenSight is a medical image viewer software. Therefore, specific information on the intended disease, condition, and patient population is not applicable.	Identical	N/A
13	Prescription or OTC	Prescription	Prescription	Prescription	Identical	N/A
14	Main System components	VSI HoloMedicine® software, and Headset (Microsoft HoloLens 2)	SurgicalAR software Headset((Microsoft HoloLens 2)	Novarad PACS Viewer software. OpenSight headset (Microsoft HoloLens) Box (23.6 cm width by 18.8 cm height by 29.6 cm long) with copper BB's	Substantially Equivalent	N/A
15	Spatial Mapping	Spatial mapping provides a representation of real-world surfaces around the device	Spatial mapping provides a representation of real-world surfaces around the device	Spatial mapping provides a representation of real-world surfaces around the device	Substantially Equivalent	N/A

16	Imaging Modality	CT, Angio CT, MRI, CBCT, PET CT and SPECT CT	CT/MR	CR, DX, CT, MR, and PET	Substantially Equivalent	N/A
17	Data Type Supported	• DICOM • OBJ • STL • JPEG • PNG • MP4 • PDF	• DICOM • Non-DICOM	OpenSight is Radiological Image Processing System, which retrieves, stores, and displays images from DICOM compliant medical imaging modalities and/or systems.	Substantially Equivalent	N/A
18	Image View/Manipulation	• Level • Reset • Image Rotate • Manually arranging object dimensions	• Image Zoom • Pan • Window Level •AutoWindow • Level • Reset • Scout Lines • Image Rotate • Image Flip • Magnify	• Image Zoom • Level • Reset • Image Rotate • Manually arranging object dimensions	Substantially Equivalent	N/A
19	Communication between Headset and computer	Wireless, encrypted	Wireless, encrypted	Wireless, encrypted	Identical	N/A
20	Data Encryption	• HTTPS • SSL	• HTTPS • SSL	256 encryption	Identical	N/A
21	Patient Demographic Display	Only the external ID that is provided to the patient after signing the patient agreement is displayed	Capable of displaying patient demographic information	Not Listed	Substantially Equivalent	N/A

22	User and Password Control	Users have own credential information to access. Users can be managed via an internal database and active directory	Users can be managed via an internal database, active directory, or parent application	Not Listed	Substantially Equivalent	N/A
23	Data Security	Stored on server	Stored on server	Stored on server	Identical	N/A
24	MPR Viewing	This viewing feature enables the display of CT, MRI, CBCT, Angio CT, PET CT and SPECT CT images into axial, coronal and sagittal orientations	This viewing feature enables the display of reformatted CT and MR images into axial, coronal and sagittal orientations	This viewing feature enables the display of reformatted CR, DX, CT, MR, and PET images into axial, coronal and sagittal orientations	Identical	N/A
25	3D Volume Rendered Viewing	This viewing feature enables the display of 3D perspective views of CT, MRI, CBCT, angio CT, PET CT and SPECT CT images 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	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.	This viewing feature enables the display of 3D perspective views of CR, DX, CT, MR, and PET 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.	Identical	N/A
26	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	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices	Identical	N/A

27	Surgical planning	Saving and loading configurations of medical images, marks, and 3D models on HMD Ability to save and load combinations and arrangement of objects displayed in the 3D space on HoloLens for planning purposes. In case it is used during surgical interventions, must not replace the role of traditional medical imaging screens.	SurgicalAR is a software platform to be used by clinicians for the visualization of medical images in 3D to allow for surgical planning activities.	Pre-operative planning of surgical option.	Substantially Equivalent	N/A
28	Creating documentation	Ability to create and view documentation on the HoloLens device, including pictures, videos and speech to text notes.	Not Reported	Not Reported	Cannot be determined	This functionality does not impact safety or efficacy of the product.
29	View of 2D pictures	Ability to view 2D pictures on HoloLens. Interact with it by dragging, scaling and rotation.	Not Reported	The patient's anatomy can be displayed in 2D mode. The surgeons can rotate and magnify the anatomy free of the patient to get a better visual picture	Substantially Equivalent	N/A
30	Help tips	It has not a feature to educate users on certain functionality that may not be obvious to a new user	It has not a feature to educate users on certain functionality that may not be obvious to a new user.	It has not a feature to educate users on certain functionality that may not be obvious to a new user.	Identical	N/A

31	Transmission Modes	Via web with Internet browsers and wireless VSI HoloMedicine® contains wireless technology and the wireless information transfer is encrypted with 256 encryption for data security	SurgicalAR is not available for use through internet browsers	OpenSight contains wireless technology using Wi-Fi 802.11ac networking standard. The wireless technology is used to stream images in a 2D format from a Novarad server onto the OpenSight headset. The wireless information transfer is encrypted with 256 encryption for data security	Substantially Equivalent	N/A
32	Support for TIF Files	VSI HoloMedicine® cannot display TIF files.	SurgicalAR can display TIF files.	OpenSight cannot display TIF files.	Identical	N/A
33	Crosshair Navigation and Synchronization	VSI HoloMedicine® has not the feature that provides a facility to synchronize and scroll through multiple views at the same time.	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	Not Reported	Identical	N/A
33	HoloNetwork	The HoloLens part of the system should contains an interactive hologram of the Earth that would display information on locations of the HoloMedicine® Expert Group members along with their title, first name, last name and country of residence.	Not Reported	Not Reported	Cannot be determined	This functionality does not impact safety or efficacy of the product.

The modifications between the VSI HoloMedicine® and the Medivis- SurgicalAR predicate are examined in detail above. ApoQlar determined that each difference between the devices resulted in no impact to the performance, safety, or efficacy of VSI HoloMedicine® when compared to Medivis-SurgicalAR.

5.6 Application of Standards

The following standards are applicable to the VSI HoloMedicine®.

Table 2: Applied Standards

STANDARD
EN ISO 13485:2016/A11:2021 Medical devices - Quality management systems
EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices
EN 62304:2006+A1:2015 Medical Device software- Software Life-Cycle Processes
IEC 62366-1:2015/AMD 1:2020 Medical devices - Part 1: Application of usability engineering to medical devices - Amendment 1
IEC 82304-1:2016 Health software - Part 1: General requirements for product safety
ISO/TR 20416:2020 Medical devices - Post market surveillance for manufacturers

5.7 Performance Data

Visual quality testing on software using the Microsoft Hololens Headset has been performed.

5.8 Conclusion

The subject device VSI HoloMedicine® is substantially equivalent to the predicate device. VSI HoloMedicine® shares a substantially equivalent design, indications for use and technology (i.e. features, materials, and principles of operation) with the predicate device and no new elements pertaining to change in safety or effectiveness have been identified.

The non-clinical and clinical data demonstrate that VSI HoloMedicine is as safe, as effective, and performs as well as the legally marketed device predicate. Moreover, software verification and validation demonstrate that the VSI Holomedicine should perform as intended in the specified use conditions.