January 29, 2026

MedicalVR B.V.
℅ Leon Doorn
Regulatory Affairs Consultant
MedQAIR Services B.V.
Rooseveltlaan 56-2
Amsterdam, 1078NL
Netherlands

Re: K252091
Trade/Device Name: Surgical Reality Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 24, 2025
Received: December 29, 2025

Dear Leon Doorn:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252091

Please provide the device trade name(s).

Surgical Reality Viewer

Please provide your Indications for Use below.

Surgical Reality Viewer is a medical imaging visualization software intended to assist trained healthcare professionals with preoperative and intraoperative visualizations, by displaying 2D and 3D renderings of DICOM compliant patient images and normal anatomic segmentations derived from patient images as well as functions for manipulation of segmentations and 3D models.

Surgical Reality Viewer assists the trained healthcare professional who is responsible for making all final patient management decisions.

The machine learning algorithms in use by Surgical Reality Viewer are intended for use on adult patients aged 22 years and over.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1 Company details

510(k) submission - Surgical Reality Viewer

Submission date	30.06.2025
Type of 510(k) Submission	Traditional
510(k) Number	K252091

Submitter details

Company Name	MedicalVR B.V.
Company Address	Markkaweg 2 2153 NB Nieuw Vennep The Netherlands

Contact person

Company contact	Chris Hordijk
Title	CEO
E-mail	chris@surgicalreality.com
Cell	+31 6 52 29 51 00

Submission correspondent

Submission correspondent	L.J. Doorn
E-mail	leondoorn@medqair.com
Cell	+31 61 10 66 42 1

2 Device details

2.1 Device identification

Common name	Surgical Reality Viewer
Proprietary / Trade name	Surgical Reality Viewer
Classification name	Automated Radiological Image Processing Software
Regulation number	892.2050
Product code	QIH
Device class	II
Review panel	Radiology
Special controls	None
510(k) number	K252091

2.2 Predicate identification

Trade name	Ceevra Reveal 3
Classification name	Automated Radiological Image Processing Software
Regulation number	892.2050
Product code	QIH
Device class	II
Review panel	Radiology
Submitter / 510(k) holder	Ceevra, Inc
510(k) number	K222676

2.3 Indications for use

Surgical Reality Viewer is a medical imaging visualization software intended to assist trained healthcare professionals with preoperative and intraoperative visualizations, by displaying 2D and 3D renderings of DICOM compliant patient images and normal anatomic segmentations derived from patient images as well as functions for manipulation of segmentations and 3D models.

Surgical Reality Viewer assists the trained healthcare professional who is responsible for making all final patient management decisions.

The machine learning algorithms in use by Surgical Reality Viewer are intended for use on adult patients aged 22 years and over.

2.4 Intended use

Surgical Reality Viewer accepts DICOM compliant images from CT or MRI scanners and segmentation files in various 3D object file formats (NifTi, OBJ, MHD, etc.).

Surgical Reality Viewer can generate preliminary segmentations of normal anatomy on demand using machine learning and computer vision algorithms. Segmentations can be edited and / or created using the various built-in 2D and 3D image manipulation functions.

The software is designed to be used by trained healthcare professionals (e.g. physicians, nurses or technicians) and is intended to assist the clinician who is ultimately responsible for making all final patient management decisions.

2.5 Equivalence

Equivalence is claimed against Ceevra Reveal 3 (K222676) which also comprises a medical image viewer device, including segmentation features driven by Artificial Intelligence algorithms.

The device indications for use, intended use and technological characteristics are considered equivalent, and therefore the performance of Ceevra Reveal 3 demonstrates safety and performance for the Surgical Reality Viewer.

Ceevra Reveal 3 is, as Surgical Reality Viewer regulated under the 'QIH' Product Code and regulated per CFR 892.2050.

3 Device description

3.1 Input

Surgical Reality Viewer accepts DICOM compliant images (e.g. CT-scans or MR images) and segmentation files in various 3D object file formats (e.g. Nifti, OBJ, MHD, STL, etc.).
The DICOM files need to be manually acquired by the user from the PACS to a local storage location from where they can be loaded by Surgical Reality Viewer.
Optionally, the DICOM files can be acquired from a service node – identified by a unique network port - that runs on the local area network and can be connected with using a secure connection.

3.2 Output

The software generates a 3D segmented view of the loaded patient data, either on a supported 2D or 3D screen. The user interface of Surgical Reality Viewer will provide tools to the user such as: pre-

operative (re)viewing of DICOM data, overlaid with segmentation, (intra/post)operative visualization of anatomical structures, 2D-viewing, volume rendering, surface rendering, immersive and interactive 3D-viewing, 2D and 3D measuring of DICOM image data, storing on a local device and anatomic labelling including segmentation tools, tools for annotations, brushing or carving (removing) of anatomical structures

3.3 Operating principle

Surgical Reality Viewer runs entirely within the customer environment, on a dedicated computer assigned by the customer. Surgical Reality Viewer allows the user to manually obtain DICOM files from within the customer system or from a specific location on the local area network. Within Surgical Reality Viewer, the user selects the relevant scan series from the Surgical Reality Viewer workspace, the software opens the scan series in the connected viewing screen to enable the healthcare professional to use and interact with the scan data.
Surgical Reality Viewer must be installed on a system that meets specific requirements.

3.4 Hardware requirements

Surgical Reality Viewer can be installed on any computer system that runs the Windows operating system, version 10 or higher. Additionally, the following minimum hardware requirements are specified:

- GPU: Nvidia GeForce 2070
- CPU: Intel i7
- Memory (RAM): 16GB

Hard drive: at least 100GB free space.

3.5 Software

Surgical Reality Viewer is able to read and write image files in the following file formats:

- DICOM files containing pixel data in JPEG format;
- NifTi files, containing segmentation voxel data;
- MHD files, also containing segmentation voxel data;
- OBJ files, which contain surface meshes;

4 Predicate comparison

4.1 Indications for use

In the following overview the comparison between the subject device's indications for use and the predicate's indications for use is provided. Any differences between the subject device and the predicate device are highlighted.

Table 1: Comparison of the Indications for Use between the subject device (Surgical Reality Viewer) and Ceevra Reveal 3

Subject Device Surgical Reality Viewer (K252091)	Predicate Ceevra Reveal 3 (K222676)
Indications for use / Intended Use	**Indications for use / Intended Use**
Surgical Reality Viewer is a medical imaging visualization software intended to assist trained	Ceevra Reveal 3 is intended as a medical imaging system that allows the processing,

healthcare professionals with preoperative and intraoperative visualizations, by displaying 2D and 3D renderings of DICOM compliant patient images and normal anatomic segmentations derived from patient images as well as functions for manipulation of segmentations and 3D models. Surgical Reality Viewer assists the trained healthcare professional who is responsible for making all final patient management decisions. The machine learning algorithms in use by Surgical Reality Viewer are intended for use on adult patients aged 22 years and over.	review, analysis, communication and media interchange of multi-dimensional digital images acquired from CT or MR imaging devices and that such processing may include the generation of preliminary segmentations of normal anatomy using software that employs machine learning and other computer vision algorithms. It is also intended as software for preoperative surgical planning, and as software for the intraoperative display of the aforementioned multi-dimensional digital images. Ceevra Reveal 3 is designed for use by healthcare professionals and is intended to assist the clinician who is responsible for making all final patient management decisions. The machine learning algorithms in use by Ceevra Reveal 3 are for use only for adult patients (22 and over). Three-dimensional images for patients under the age of 22 or of unknown age will be generated without the use of any machine learning algorithms.

The subject device and the predicate device are indicated to view medical images pre- and intraoperatively acquired by CT or MRI, generate segmentations of supported normal anatomical structures, and indicated for use by the same user, and on the same patient group, with a view to assist the clinician.

4.2 Technological characteristics

In the following Table 2, the technological characteristics of the subject device (Surgical Reality Viewer) are compared against the technological characteristics of the predicate device (Ceevra Reveal 3). Any differences between the two devices are evaluated for their potential implications with regards to the demonstration of Safety and or Performance.

Table 2: Comparison of Technological Characteristics between the Subject device (Surgical Reality Viewer) and the Predicate Device (Ceevra Reveal 3)

Technological characteristic	Subject Device Surgical Reality Viewer (K252091)	Predicate Ceevra Reveal 3 (K222676)
Product Code	QIH	QIH
Product Regulation	892.2050	892.2050
Supported Imaging Modalities	CT & MRI	CT & MRI
Intended Users	Healthcare Professionals	Healthcare Professionals
Image Analysis Features	Interactive manipulation and 3D visualization	Interactive manipulation and 3D visualization
Pre-operative viewing of 3D images	Yes	Yes

Intra-operative viewing of 3D images	Yes	Yes
Real-time inter-operative guidance, navigation or otherwise integrated with surgical instruments	No	No
Segmentation work performed by	Medical Professional	Internal Operator
Built-in features for end-user to compare CT/MRI to device output	No	No
Quantitative outputs calculated by device	No	No
Semi-automatic segmentation of abnormal anatomy	No	No
Semi-automatic segmentation of supported normal anatomy	Yes	Yes

The subject device includes the exact same technological characteristics as the predicate device. There are no concerns identified by MedicalVR with regards to the features and functionalities of the device which require additional Safety and or Performance data.

As the device is supported by Artificial Intelligence to prepopulate semi-automatic segmentations of supported anatomy structures, specific bench tests are executed to demonstrate in verification testing:

- Segmentation accuracy
- Generalizability (across different sub-groups)

In addition thereto, through user validation testing, the ease of use of the software and the segmentations generated by the use of the subject device (Surgical Reality Viewer) will be demonstrated.

4.3 Performance data

4.3.1 Software verification and validation

Surgical Reality Viewer is developed in line with the IEC 62304/2006/Amd 1: 2015 standard on 'Medical device software - Software life cycle processes' in addition to application of the supporting FDA guidance documents on premarket submissions for software, the IEC 81001-5-1 on 'Health software and health IT systems safety, effectiveness and security - Part 5-1: Security — Activities in the product life cycle' and the FDA guidance regarding cybersecurity on quality system considerations and content of premarket submissions.

4.3.2 Machine learning segmentation

Surgical Reality Viewer includes multiple machine learning algorithms which support the segmentation of anatomical structures within CT chest images for 3D visualization. Each of the algorithms has been trained and tuned on curated datasets representative of the intended patient population.

Surgical Reality Viewer's performance has been tested on a clinical testing dataset with a total of 102 CT images. A CT image was either part of the tuning or testing dataset and not in both. Each study belonged uniquely to a single patient subject. Each study has been segmented by trained professionals and the segmentations were verified by thoracic surgeons with a minimum of 2 years professional working experience. In total 60 (n=60) scans were obtained from the United States. Representative numbers in subgroups were included to ensure proper assessment of performance

amongst patient characteristic subgroups (e.g. geographical location, age, sex, ethnicity,) and imaging characteristic subgroups (e.g. CT scanner manufacturer, contrast vs non-contract enhanced, CT slice-thickness) and acquisition timeframes.

In total 53% of the participants where the age was reported were aged under 60 years of age, 25% between 60 and 70 years of age and 22% over the age of 70. Of 38% of the participants, age was unknown. From the participants for which gender was reported (n=63) 51% were male and 49% were female. Scanner manufacturers included Siemens, GE Healthcare, Philips, Canon and Toshiba. Ethnicity of patients in the datasets was reasonably correlated to the overall US population.

Performance was verified by comparing segmentations generated by the machine learning models against ground truth segmentations generated by trained professionals.

The performance of the machine learning models, characterized by the Sørensen–Dice coefficient (DSC) Conclusion. Lobe segmentation accuracy resulted in an average DICE of 0.97 (LUL: 0.98, LLL: 0.98, RUL: 0.98, RLL: 0.98, RML: 0.96), Vessel segmentation accuracy resulted in an average DICE of 0.84 (Artery: 0.84, Vein: 0.83), Airway segmentation accuracy resulted in an average DICE of 0.96, Aorta segmentation resulted in an accuracy of 0.96, Pulmonary segmentation accuracy resulted in an average DICE 0.85 (left segments: 0.85, right segments: 0.85).

In addition, to verify the usability and clinical usefulness of the segmentations generated by Surgical Reality Viewer medical professionals were tasked to qualitatively score the suitability of the segmentations provided through the Viewer. The score ranged from 1 (minimum) to 5 (maximum) Airways segmentations scored 4.8, artery segmentations scored 4.8, vein segmentations scored 4.9, lobe Segmentations scored 5.0, pulmonary lobe segments scored with 4.7 and aorta segmentations scored 5.0.

5 Conclusion

Surgical Reality Viewer is deemed to be substantially equivalent to its predicate device based on indications for use, technological characteristics and performance testing.

The Surgical Reality Viewer does not raise new questions related to safety or effectiveness.

6 Version History

Version control is handled electronically. In this chapter, only a summary between the different versions is provided to help the reader easily identify the differences between versions.

Version	Summary of change
2.0	Updated to reflect the required changes for the 510(k) summary
1.0	Initial version.