March 30, 2026

Avatar Medical
Adeline Francois
VP QARA and Clinical Affairs
11 Rue Lourmel
Paris, 75015
France

Re: K253950
Trade/Device Name: Avatar Medical Vision
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 27, 2026
Received: February 27, 2026

Dear Adeline Francois:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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, Ph.D.
Assistant Director
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. | K253950 |

Please provide the device trade name(s).

Avatar Medical Vision

Please provide your Indications for Use below.

Avatar Medical Vision is intended as a medical imaging system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from CT or MR imaging devices. It is also intended as software for preoperative surgical planning, and as software for the intraoperative display of the aforementioned multi-dimensional digital images on a standard (non-stereoscopic) screen in the operating room, and on an autostereoscopic screen or VR headset in a non-sterile room. Avatar Medical Vision is designed for use by healthcare professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.

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

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

# 510(k) Summary

## Device Name: Avatar Medical Vision

# 5.1 General Information

**Table 5A: Submission Correspondent**

| | |
|---|---|
| **510(k) Sponsor** | Avatar Medical |
| **Address** | 11 rue de Lourmel<br>75015 Paris France |
| **Correspondence Person** | Francois Adeline<br>VP QARA and Clinical Affairs |
| **Contact Information** | Email: adeline@avatarmedical.ai |
| **510(k) Summary Date** | 8 December 2025 |

# 5.2 Subject Device

**Table 5B: Subject Device**

| | |
|---|---|
| **Proprietary Name / Trade Name** | Avatar Medical Vision |
| **Common Name** | System, Image Processing, Radiological |
| **Classification Name / Regulation Name** | Medical Image Management and Processing System |
| **Regulation Number** | 21 CFR 892.2050 |
| **Product Code** | LLZ |
| **Regulatory Class** | II |

# 5.3 Predicate Device

**Table 5C: Predicate Device**

| | |
|---|---|
| **Proprietary Name / Trade Name** | AVATAR MEDICAL Software V1 |
| **Common Name** | System, Image Processing, Radiological |
| **Premarket Notification** | K222035 |
| **Classification Name / Regulation Name** | Medical Image Management and Processing System |
| **Regulation Number** | 21 CFR 892.2050 |
| **Product Code** | LLZ |
| **Regulatory Class** | II |

# 5.4 Device Description

Avatar Medical Vision is a software-only device that allows medical professionals to review CT and MR image data in three-dimensional (3D) format on a standard (non-stereoscopic) or autostereoscopic computer screen and/or in virtual reality (VR) interface. The 3D and VR images are accessible through the software desktop application, on a standard (non-stereoscopic) or autostereoscopic computer screen, and, if desired, through compatible VR headsets. Images are used by users for preoperative surgical planning and for display during intervention/surgery.

The Avatar Medical Vision product is to be used to assist in medical image review. Intended users are medical professionals, including imaging technicians, clinicians and surgeons.

Avatar Medical Vision includes three main software-based user interface components:

- the Splash Screen Interface (includes DICOM query),
- the Desktop Interface (includes 2D Interface, 3D Interface, and Autostereoscopic Interface),
- the VR Interface.

The Splash Screen Interface and Desktop Interface run on a compatible off-the-shelf (OTS) workstation provided by the hospital and only accessed by authorized personnel.

The Splash Screen Interface contains a graphical user interface where a user can retrieve DICOM-compatible medical images locally or from a Picture Archiving Communication System (PACS) or DICOM Server. Upon loading a DICOM series, the user is presented with the main Desktop Interface, which itself comprises a 2D and 3D Interface, with the option of switching to the VR and Autostereoscopic dedicated Interfaces. Users are able to make measurements, annotations, and apply fixed and manual image filters. Additionally, the

Desktop Interface can be accessed through the Avatar Hub, a streaming service that allows users to securely access their remote computer where Avatar Medical Vision is installed.

The Autostereoscopic Interface is accessible via a compatible autostereoscopic display to allow users to review the medical images in a 3D autostereoscopic format. This interface is shown in the Desktop Interface. This 3D autostereoscopic format can be viewed only when the user connects a compatible autostereoscopic screen directly to the workstation being used to view the Desktop Interface. Avatar Medical Vision's autostereoscopic mode is compatible solely with the following autostereoscopic monitor:

- Barco Eonis 3D MDRC-8127

The VR Interface is accessible via a compatible OTS headset to allow users to review the medical images in a VR format. VR formats can be viewed only when the user connects a compatible VR headset directly to the workstation being used to view the Desktop Interface. Avatar Medical Vision's virtual reality (VR) mode is compatible solely with the following VR headsets:

- HTC Vive XR Elite
- Meta Quest 3

The 3D images generated using Avatar Medical Vision are intended to be used in relation to surgical procedures in which CT or MR images are used for preoperative planning and/or during intervention/surgery.

The intraoperative use of Avatar Medical Vision solely corresponds to the two following cases:

- Display of the Avatar Medical Vision Desktop Interface on existing standard (non-stereoscopic) monitors/screens in the operating room. The autostereoscopic screen is not intended for installation in the operating room to display Avatar Medical Vision.
- Use in a non-sterile image review room accessible from the operating room during the procedure (Avatar Medical Vision operates on VR headsets and on autostereoscopic screen, which are not approved to be used in the sterile environment of the operating room).

*Usage During Interventional and Surgical Procedures*

Avatar Medical Vision is not meant to be used in a sterile environment.

Avatar Medical Vision is not meant to register 3D images to patients.

Two usage scenarios of Avatar Medical Vision software are possible during an interventional or surgical procedure:

1. Inside the operating room

The Desktop Interface (no VR) can be displayed on a standard (non-stereoscopic) monitors/screens (previously installed respecting the management of sterility) inside the operating room. The autostereoscopic screen is not intended for installation in the operating room.

It is not expected that users will analyze the image, optimize filters, and realize measurements in this intraoperative context. This usage is for visualizing results of a previous surgery planning session.

The user will follow their scrub-in and scrub-out facility protocols when exiting and entering the sterile field of the operating room.

2. Outside the operating room

The full software experience, including VR and autostereoscopic screen, can be accessed in an adjacent non-sterile image review room. In this usage, the user will need to scrub-out to access the review room and, after review, scrub-in following their facility protocols as required. The user will not be in contact nor in the presence of the patient while wearing the VR headset or using the autostereoscopic screen.

The software is not meant to be used with the user's hands on the patient during an interventional or surgical procedure.

# 5.5 Indications For Use

Avatar Medical Vision is intended as a medical imaging system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from CT or MR imaging devices. It is also intended as software for preoperative surgical planning, and as software for the intraoperative display of the aforementioned multi-dimensional digital images on a standard (non-stereoscopic) screen in the operating room, and on an autostereoscopic screen or VR headset in a non-sterile room. Avatar Medical Vision is designed for use by healthcare professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.

# 5.6 Comparison of Technological Characteristics

**Table 5D: Comparison of Characteristics**

| **Feature/ Function** | **Subject Device: Avatar Medical Vision** | **Predicate Device: AVATAR MEDICAL Software V1 (K222035)** |
|---|---|---|
| **Intended Users** | Healthcare Professionals | Healthcare Professionals |
| **Intended Environment** | Healthcare facilities such as hospitals and clinics | Healthcare facilities such as hospitals and clinics |
| **Device Class** | Class II | Class II |
| **Preoperative Use** | Yes | Yes |
| **Intraoperative Display** | Yes | Yes |
| **Type of display** | • standard (non-stereoscopic);<br>• Auto-stereoscopic display;<br>• VR headset. | • standard (non-stereoscopic);<br>• VR headset. |

| Feature/ Function | Subject Device: Avatar Medical Vision | Predicate Device: AVATAR MEDICAL Software V1 (K222035) |
|---|---|---|
| **Image Analysis Features** | Interactive manipulation, manual segmentation, create annotations and measurements | Interactive manipulation, manual segmentation, create annotations and measurements |
| **Measurements** | Yes - linear, non-linear and volumetric measurements only | Yes - linear and diameter measurements only |
| **Remote streaming** | No | Yes |
| **Pan image** | Pan image in any direction | Pan image in any direction |

# 5.7 Predicate Device Comparison

The subject device and predicate device have similar intended use in that they are both intended for viewing CT and MR data in multi-dimensional views as well as for preoperative and intraoperative surgical planning using similar technologies. Additionally, both devices have similar technological characteristics with only minor differences that do not raise questions of safety or effectiveness.

# 5.8 Performance Data

Safety and performance of the Avatar Medical Vision has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with EN 62304:2006/ A1:2015 - Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “Content of Premarket Submission for Management of Cybersecurity in Medical Devices.”

All functional and performance tests were all performed with the minimum hardware configuration and the specified operating systems. If the test required the use of an autostereoscopic display, the minimum hardware configuration was associated with the compatible autostereoscopic display.

Measurements performances: Measurement performance testing (linear, non-linear and landmark positioning), was conducted by leveraging reference digital phantoms. The volume accuracy compared the average volume measurements to the objects’ known volumes.

Display quality performances: The quality of the display for the VR/autostereoscopic experiences was successfully evaluated for visual evaluation of luminance, contrast and resolution.

System performances: The fluidity of the VR/autostereoscopic experiences was assessed by evaluating the average Frame Per Second rate. The average FPS was superior to the specific threshold for the minimal hardware configuration. The file upload performance was assessed by evaluating the time needed to load an image in Avatar Medical Vision.

Filters performances: The functioning of the filter technology was assessed by visual inspection.

Additional VR Headset display performances: Additional optical testing was conducted on compatible VR platforms in accordance with IEC 63145-20-20. The homogeneity of luminance, resolution, and contrast was evaluated as acceptable for the intended use in the center of the displays for the specified viewing conditions.

Additional autostereoscopic display performances: Testing was conducted on the compatible autostereoscopic display by the manufacturer Barco to ensure adequate performance regarding luminance, contrast and crosstalk.

# 5.9 Statement of Substantial Equivalence

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the Avatar Medical Vision raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.