Avatar Medical
℅ Rory Carrillo
Quality and Regulatory Consultant
Cosm
45 Bartlett St.
SAN FRANCISCO CA 94110

May 24, 2023

Re: K222035
Trade/Device Name: Avatar Medical Software V1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 21, 2023
Received: April 24, 2023

Dear Rory Carrillo:

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, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of 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)*
K222035

Device Name
AVATAR MEDICAL Software V1

Indications for Use *(Describe)*
AVATAR MEDICAL Software V1 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. AVATAR MEDICAL Software V1 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.

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

1. General Information

K222035

510(k) Sponsor	Avatar Medical
Address	11 rue de Lourmel 75015 Paris France
Correspondence Person	Rory A. Carrillo Quality and Regulatory Consultant Cosm
Contact Information	Email: rory@cosmhq.com Phone: 562-533-7010
Date Prepared	November 22, 2022

2. Subject Device

Proprietary Name	Avatar Medical Software V1
Common Name	AMS V1
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Proprietary Name	Ceevra Reveal 2.0
Premarket Notification	K173274
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	LLZ
Regulatory Class	II

4. Device Description

The Avatar Medical Software V1 (AMS V1) is a software-only device that allows trained medical professionals to review CT and MR image data in three-dimensional (3D) format and/or in virtual reality (VR) interface. The 3D and VR images are accessible through the software desktop application and, if desired, through compatible VR headsets which are used by users for preoperative surgical planning and for display during intervention/surgery.

The AMS V1 product is to be used to assist in medical image review. Intended users are trained medical professionals, including imaging technicians, clinicians and surgeons.

AMS V1 includes two main software-based user interface components, the Desktop Interface and the VR Interface. The Desktop Interface runs on a compatible off-the-shelf (OTS) workstation provided by the hospital and only accessed by authorized personnel. The Desktop Interface contains a graphical user interface where a user can retrieve DICOM-compatible medical images locally or on a Picture Archiving Communication System (PACS). Retrieved CT and MR images can be viewed in 2D and 3D formats. Users are able to make measurements, annotations, and apply fixed and manual image filters.

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. Additionally, AMS V1 enables the intended users to remotely stream the Desktop Interface to another workstation on the same local area network (LAN).

The 3D images generated using AMS V1 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 the AMS V1 solely corresponds to the two following cases:

- Display of the AMS V1 Desktop Interface on existing monitors/screens in the operating room
- Use in a non-sterile image review room accessible from the operating room during the procedure (AMS V1 operates on VR headsets which are not approved to be used in the sterile environment of the operating room)

Usage During Interventional and Surgical Procedures

The AVATAR MEDICAL Software V1 is not meant to be used in a sterile environment.

The AVATAR MEDICAL Software V1 is not meant to register 3D images to patients.

Two usage scenarios of the AVATAR MEDICAL Software V1 software are possible during an interventional or surgical procedure:

1. Inside the operating room

   The Desktop Interface (no VR) can be displayed on a computer monitor (previously installed respecting the management of sterility) inside 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, 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

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

5. Intended Use and Indications for Use

AVATAR MEDICAL Software V1 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. AVATAR MEDICAL Software V1 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.

6. Comparison of Technological Characteristics

Feature/ Function	**Subject Device:** AMS V1	**Predicate Device:** Ceevra Reveal 2.0 (K173274)
Intended Users	Health care Professionals	Health care Professionals
Intended Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Device Class	Class II	Class II

Feature/ Function	Subject Device: AMS V1	Predicate Device: Ceevra Reveal 2.0 (K173274)
Preoperative Use	Yes	Yes
Intraoperative Display	Yes	Yes
Image Analysis Features	Interactive manipulation, filtering, create annotations and measurements	Interactive manipulation and segment
Measurements	Yes - linear and diameter measurements only	No
Remote Streaming	Yes	No
Pan image	Pan image in any direction	Pan image in any direction
PIN Code	Yes, for remote streaming only	Optional 4-digit security code

7. Predicate Device Comparison

The subject device and predicate device have similar indications for 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.

8. Performance Data

Safety and performance of the AMS V1 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 *ANSI AAMI IEC 62304:2006/A1:2016 - 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 testing occurred on the minimum hardware configuration and the specified operating systems and VR platforms. Measurement performance testing was conducted by leveraging reference digital phantoms and the comparison with a cleared device (Osirix MD K101342). The table below summarizes the acceptance criteria for the measurement tools. The quality of the display was successfully evaluated against the AAPM guidance recommendation for visual evaluation of luminance and contrast . Additional optical testing was conducted on compatible VR platforms as per IEC63145-20-20 and passed as expected. The homogeneity of luminance, resolution, and contrast was evaluated as acceptable per these standards in the center of the displays for the specified VR platforms. The functioning of the filter technology was assessed by visual inspection. Using a reference DICOM, the opacity and color of specific voxels in the image was demonstrated to be controllable as intended by the filtering principle, which is similar to the cleared device Osirix MD (K101342) . The fluidity of the VR experience was assessed by evaluating the average Frame Per Second rate. The averaged FPS was superior to the specific threshold for the minimal hardware configuration.

Feature/ Function	**Tool in Subject Device:** AMS V1	**Tool in Reference Device:** Osirix MD (K101342)	**Acceptance criteria**
Linear Measurements (polylines)	Curve	Close Polygon	No statistical difference between distributions of measurements obtained for AMS V1 or the reference device Osirix MD, as evaluated per t-test statistics. Tests performed for a series of objects in reference MR and CT phantom images.
Diameter Measurements	Ruler	Length	

9. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the AMS V1 raises no new questions of safety and effectiveness and demonstrates substantial equivalence to the predicate device in terms of safety, effectiveness, and performance.