Sira Medical, Inc.
% Richelle Helman
Senior Director
MEDIcept. INC,
200 Homer Avenue
ASHLAND, MASSACHUSETTS 01721

February 1, 2024

Re: K232339
Trade/Device Name: Augmented Reality Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 4, 2023
Received: January 11, 2024

Dear Richelle Helman:

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.

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
Assistant Director
DHT8B: Division of Radiologic 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)*
K232339

Device Name
Augmented Reality Application

Indications for Use *(Describe)*
Sira Medical Augmented Reality Application is intended as a medical imaging system that allows the processing, review, analysis, and communication of augmented reality images acquired from the same data used to generate conventional CT scans and MRIs. Sira Medical software is designed for preoperative surgical planning and intended to be used by trained and qualified clinicians who are responsible for making 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K232339

Date:	31-January-2024
Company:	Sira Medical, Inc. 14 Stanford Heights Avenue San Francisco, CA 94127 Phone: (917) 864-5083
Official Contact:	Richelle Helman Senior Director, Regulatory rhelman@medicept.com
Proprietary or Trade Name:	Augmented Reality Application
Regulation Name:	Medical Image Management and Processing System
Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050, Class II Classification Product Code: LLZ
Predicate Device:	K211443: AIbolit Technologies, LLC, Aibolit 3D+

Device Description:
The Sira Medical Augmented Reality Application is used for viewing and manipulating 3D models created by the Sira 3D Image Preparation Service from customer-supplied anonymized (de-identified) imaging in Augmented Reality (AR) on a Head Mounted Display (HMD). The application allows the user to manipulate one or more 3D models in real time in an Augmented Reality (AR) environment. The user can view the model, adjust the orientation, scale, rotate and position the models within the AR visual space. Models can be sliced to create separate objects or merged together to create a single object. These models are used for preoperative surgical planning but are not used intraoperatively (during surgical procedures).

Indications for Use:
Sira Medical Augmented Reality Application is intended as a medical imaging system that allows the processing, review, analysis, and communication of augmented reality images acquired from the same data used to generate conventional CT scans and MRIs. Sira Medical software is designed for preoperative surgical planning and intended to be used by trained and qualified clinicians who are responsible for making patient management decisions.

Substantial Equivalence:
The Sira Medical, Inc. Augmented Reality Application is substantially equivalent to the predicate device, the AIbolit Technologies, LLC, Aibolit 3D+ (510(k) K211443). The table below presents the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Characteristic	**Subject Device:** Augmented Reality Application	**Predicate Device:** Aibolit 3D+ [510(k) K211443]
Indications for Use	Sira Medical Augmented Reality Application is intended as a medical imaging system that allows the processing, review, analysis, and communication of augmented reality images acquired from the same data used to generate conventional CT scans and MRIs. Sira Medical software is designed for preoperative surgical planning and intended to be used by trained and qualified clinicians who are responsible for making patient management decisions.	Aibolit 3D+ is intended as a medical imaging system that allows the processing, review, analysis, communication and media interchange of multidimensional digital images acquired from CT imaging devices. It is also intended as software for preoperative surgical planning, training, patient information and as software for the intraoperative display of the multidimensional digital images. Aibolit 3D+ 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.
Intended Use	Provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis or patient management. The software components may provide advanced or complex imaging processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include 3D visualization.	Provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis or patient management. The software components may provide advanced or complex imaging processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include 3D visualization.
Mechanism of Action	Capture and enhancement of (DICOM) digital images via software-based conversion to 2-D and 3-D anatomical structure images that can be manipulated for viewing	Capture and enhancement of (DICOM) digital images via software-based conversion to 2-D and 3-D anatomical structure images that can be manipulated for viewing
Intended Users	Health care professionals	Health care professionals
Intended Use Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Format of Captured Images	DICOM	DICOM
Security	Data coded and HIPAA compliant	Data coded and HIPAA compliant

Characteristic	**Subject Device:** Augmented Reality Application	**Predicate Device:** Aibolit 3D+ [510(k) K211443]
Form of Device	Sira Medical is a software only device that permits electronic image uploads, provides image conversion and allows viewing on a head mounted device.	Aibolit 3D+ is a software only device that permits electronic image uploads, provides image conversion and allows viewing on a mobile device or standard computer monitor.
Image processing	High-definition digital images	High-definition digital images
Functions	Generation of 2D and 3D images from DICOM data Organ segmentation and structure identification Dimensional and volume references Multi-axis image rotation Organ transparency	Generation of 2D and 3D images from DICOM data Organ segmentation and structure identification Dimensional and volume references Multi-axis image rotation Organ transparency Organ retraction animation
Body contact	None	None
User Interface and System Work-Flow	Physician uploads DICOM images and specifies desired anatomical segments of interest Radiologist annotates sample (segments) images Software facilitates annotation of available images under guidance and control by the Radiologist Imaging technician generates multi-axis rotatable image and retraction model Radiologist reviews images generated by imaging technician and returns output file to requesting physician	Physician uploads DICOM images and specifies desired anatomical segments of interest Radiologist annotates sample (segments) images AI software facilitates annotation of available images under guidance and control by the Radiologist Imaging technician generates multi-axis rotatable image and retraction model Radiologist reviews images generated by imaging technician and returns output file to requesting physician
External / Internet Connections	Web-based software	Web-based software
Image Uploading	By requesting physician	By requesting physician
Other User Inputs	List of organ structures to be annotated and displayed, patient ID and demographics	List of organ structures to be annotated and displayed, patient ID and demographics

Characteristic	Subject Device: Augmented Reality Application	Predicate Device: Aibolit 3D+ [510(k) K211443]
Image Segmentation	By Radiologist (MD) – Manual annotation is done for all image data	By Radiologist (MD) – Manual annotation is done for all CT slices with optional use of AI/ML algorithms as determined by Radiologist and with Radiologist's approval
Organ Identification	By Radiologist	By Radiologist
3D Image generation	3D image file generated by 3rd party software (Osirix MD) following Radiologist review and approval of annotation	3D image file generated by 3rd party software (3D Slicer) following Radiologist review and approval of annotation
Organ structure identification	Proprietary software assigns color coding to each structure identified by Radiologist and displays color-coded image	Proprietary software assigns color coding to each structure identified by Radiologist and displays color-coded image with labeled key to color/structure identity
Image editing permission	Only the radiologist can alter or edit images following review – User physicians cannot edit images - Physicians have option to show or hide organs on display	Only the radiologist can alter or edit images following review – User physicians cannot edit images - Physicians have option to show or hide organs on display
Device Output Devices	3D image can be displayed on augmented reality 3D headset	3D image can be displayed on standard monitor
Supplemental outputs	Organ structure dimensions, volume, organ labels, patient ID, CT date and demographics	Organ structure dimensions, volume, organ labels, patient ID, CT date and demographics
Output image manipulation by user	Physician user can show or hide individual organ structures, zoom capability, rotational capability and transparency capability	Physician user can show or hide individual organ structures, zoom capability, rotational capability and transparency capability

From the comparison form above, the subject device and predicate device have the same intended use and the same operating principle as a medical imaging system for the display of multidimensional digital images. The minor differences in the devices do not raise different questions of safety or effectiveness.

Non-clinical performance testing:
Bench / Performance Testing –

- Software verification and validation testing were conducted as required by IEC 62304 and documentation was provided as recommended by FDA Guidance "Content of Premarket Submissions for Software Contained in Medical Devices".
- Human factors testing was conducted in compliance with the requirements of IEC 62366-1 and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". Test participants representing the intended users of the device were included in the human factors validation testing. Observational data as well as interview

data were recorded. The observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device is safe and effective for the intended users, uses and use environments.

The results demonstrated that the Sira Medical, Inc. Augmented Reality Application performs according to its specifications and functions as intended.

Substantial Equivalence Conclusion

The Sira Medical, Inc. Augmented Reality Application has the same intended use and the same operating principle as the predicate device. The performance testing demonstrated that the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.