See-Mode Technologies Pte. Ltd.
℅ Mr. Alan Donald
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive, Suite 800
SAN DIEGO CA 92108

September 16, 2020

Re: K201369
Trade/Device Name: AVA (Augmented Vascular Analysis)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 17, 2020
Received: August 19, 2020

Dear Mr. Donald:

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 post-marketing 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201369

Device Name
AVA (Augmented Vascular Analysis)

Indications for Use *(Describe)*
See-Mode AVA (Augmented Vascular Analysis) is a stand-alone, image processing software for analysis, measurement, and reporting of DICOM-compliant vascular ultrasound images obtained from carotid and lower limb arteries. The analysis includes segmentation of vessels walls and measurement of the intima-media thickness (IMT) of the carotid artery in B-Mode images, finding velocities in Doppler images, and reading annotations on the images. The software generates a vascular ultrasound report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. The client software is designed to run on a standard desktop or laptop computer. See-Mode AVA is intended to be used by trained medical professionals, including but not limited to physicians and medical technicians. The software is not intended to be used as an independent source of medical advice, or to determine or recommend a course of action or treatment for patients.

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

This "510(k) Summary" was prepared per section 807.92(c).

ADMINISTRATIVE INFORMATION

Date of Preparation: September 14, 2020
Prepared by: Sadaf Monajemi, PhD. Cofounder and Director
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: AVA (Augmented Vascular Analysis)
Common Name: Picture archiving and communications system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological
Review Panel: Radiology
Regulatory Class: Class II
Product Code: LLZ

INTENDED USE

Analysis and reporting of vascular ultrasound images.

INDICATIONS FOR USE

See-Mode AVA (Augmented Vascular Analysis) is a stand-alone, image processing software for analysis, measurement, and reporting of DICOM-compliant vascular ultrasound images obtained from carotid and lower limb arteries. The analysis includes segmentation of vessels walls and measurement of the intima-media thickness (IMT) of the carotid artery in B-Mode images, finding velocities in Doppler images, and reading annotations on the images. The software generates a vascular ultrasound report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. The client software is designed to run on a standard desktop or laptop computer.
See-Mode AVA is intended to be used by trained medical professionals, including but not limited to physicians and medical technicians. The software is not intended to be used as an independent source of medical advice, or to determine or recommend a course of action or treatment for patients.

DEVICE DESCRIPTION

See-Mode AVA (Augmented Vascular Analysis) is a standalone software for analysis and reporting of vascular ultrasound images. There is no dedicated medical equipment required for operation of this software except for an ultrasound machine that is the source of image acquisition. The software runs on a standard off-the-shelf computer and is accessible within a web browser.
See-Mode AVA takes as input DICOM-compliant vascular ultrasound images. The software uses proprietary algorithms for image analysis, including segmentation of vessel walls and measurement of the intima-media thickness (IMT) of the carotid artery in B-Mode images and finding peak systolic and end diastolic velocities (PSV and EDV) from Doppler images. The software generates a vascular ultrasound report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. Any information within this report must be fully reviewed and approved by a qualified clinician before the vascular ultrasound report is finalized.
See-Mode AVA is not intended to be used as an independent source of analysis and reporting vascular ultrasound images. Any information provided by the software has to be reviewed by a qualified clinician (including sonographers, radiologists, neurologists, and cardiologists) and can be modified to correct any possible mistakes. The software provides multiple methods for performing quality control and modification of image analysis results. When the vascular ultrasound report is finalized by a qualified clinician, See-Mode AVA exports the report. This report can be used adjunctly with other medical data by a physician to help in the assessment of the cardiovascular health of the patient.

SUBSTANTIAL EQUIVALENCE

1. **Predicate Device**

Manufacturer: AtheroPoint LLC
Trade Name: AtheroEdge
510(k) Identifier: K122022
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological
Review Panel: Radiology
Regulatory Class: Class II
Product Code: LLZ
Date Cleared: September 26, 2012

2. **Tabular Comparison of Features and Specifications of the AVA Device and Predicate Device**

	Subject Device	Predicate Device	Notes
Manufacturer	See-Mode Technologies Pte. Ltd.	Atheropoint LLC	
Product name	See-Mode AVA (Augmented Vascular Analysis)	AtheroEdge	
510(k) number	Via this submission	K122022	
Classification	Class II - 90 LLZ 892.2050/LLZ	Class II - 90 LLZ 892.2050/LLZ	Same
Intended Use	Analysis and reporting of vascular ultrasound images	Analysis and reporting of vascular ultrasound images	Same
Indications for Use	See-Mode AVA (Augmented Vascular Analysis) is a stand-alone, image processing software for analysis, measurement, and reporting of DICOM-compliant vascular ultrasound images obtained from carotid and lower	The AtheroEdgeTM software is a Windows-based application program used on a personal computer for an automatic measurement of the	Nearly the same. See discussion below.

	limb arteries. The analysis includes segmentation of vessels walls and measurement of the intima-media thickness (IMT) of the carotid artery in B-Mode images, finding velocities in Doppler images, and reading annotations on the images. The software generates a vascular ultrasound report based on the image analysis results to be reviewed and approved by a qualified clinician after performing quality control. The client software is designed to run on a standard desktop or laptop computer. See-Mode AVA is intended to be used by trained medical professionals, including but not limited to physicians and medical technicians. The software is not intended to be used as an independent source of medical advice, or to determine or recommend a course of action or treatment for patients.	Intima-Media Thickness (IMT) of the carotid artery from images obtained from ultrasound systems.	
Image Source	Ultrasound images	Ultrasound images	Same
Rx only?	Yes	Yes	Same
Operating Platform	The software runs on a standard "off-the-shelf" computer and can be accessed within the software client web browser.	Stand-alone application program for use on a personal computer with Microsoft Windows.	Nearly the same. See discussion below.
Image Format	DICOM	DICOM, JPEG and Windows BMP	Same
Image storage and report generation	Yes	Yes	Same
Automatic distance measurement of the Intima- Media thickness of carotid artery	Yes	Yes	Same

Image Compression	JPEG Loss-less	JPEG Loss-less	Same
Target Population	As the device is prescription only, the target population of the device is anyone in the general population that receives the relevant carotid or lower limb artery ultrasound scan	As the device is prescription only, the target population of the device is anyone in the general population that receives the relevant carotid ultrasound scan	Same

3. Discussion of Similarities and Differences and Explanation of Differences

Similarities:

Both devices have the same intended use and are indicated for the same use -- providing a software based user's interface to view, process, and analyze carotid ultrasound images. Both devices use algorithms to segment and measure intima media thickness, and can store the results and generate reports.

The predicate device was cleared based on non-clinical supportive information, clinical images and data. Comparative non-clinical test results demonstrate that See-Mode AVA performs at least equivalently to the predicate device. Acceptance criteria and verification and validation data demonstrate that the device performs per its specifications and indications for use.

The comparison of technological characteristics, non-clinical performance data, clinical images, and software validation data demonstrate that See-Mode AVA is as safe, and effective when compared to the predicate device that is currently marketed for the same intended use and indications for use.

Differences:

1. Image processing algorithm:

The predicate device was designed using technology that was available a few years ago, [i.e., software programming using traditional image processing algorithms

(such as edge tracking and gradient based algorithms)]. See references cited below for the predicate device[1, 2].

With the advancements in the field of artificial intelligence and machine learning, See-Mode AVA incorporates a logical update to use artificial intelligence for image analysis. Machine learning and artificial intelligence (AI) have been proven as an efficient and accurate method for analyzing medical images and is used among a wide range of legally marketed medical devices. See-Mode AVA benefits from the established machine learning methods to analyze ultrasound images and represents an improved technology that provides a clinically meaningful advantage over the legally marketed predicate device. See-Mode has conducted an Analytical Study to substantiate this claim (see Performance Data below).

2. Operating platform:

The predicate device is designed to be installed on a personal computer with Microsoft Windows.

See-Mode AVA benefits from the advancements of cloud computing and is a software program running on a cloud platform and can be accessed using multiple platforms, including Windows.

Although the Predicate device slightly differs from the Subject device with regards to the operating platform, there are several examples of FDA cleared medical devices that use cloud platforms for medical image analysis (examples: Aidoc Briefcase Software - 510(k) Number K180647, CardioLogs ECG Analysis Platform - 510(k) Number K170568, Arterys Cardio DL - 510(k) Number K163253). Based on this, and in combination with identification of hazards and appropriate risk controls related to this difference, we conclude that this difference in technology platform has no adverse impact on the safety or efficacy of the Subject device. Additionally, the fact that all users are utilizing the same (e.g., latest version) of the AVA software is considered to be an improvement to both safety and efficacy when compared to the predicate device.

3. Analyzing lower limb ultrasound images:

[1] "Completely Automated Multiresolution Edge Snapper—A New ...." https://ieeexplore.ieee.org/iel5/83/6151934/06026248.pdf.
[2] "Automated high-performance cIMT measurement techniques using ...." https://www.ncbi.nlm.nih.gov/pubmed/22255864.

See-Mode AVA can be used for analysis and reporting of lower limb ultrasound scans. Using the text recognition and the signal processing algorithm, the software can read doppler velocities and annotations from the images, detect the waveform type, populate them in the report and generate qualitative drawings of the stenosis in lower limb arteries based on doppler velocity ratios.

PERFORMANCE DATA

Safety and performance of the subject device has been evaluated, verified and validated according to the software specifications and applicable performance standards. See-Mode Technologies has performed software verification and validation testing for the subject device according to the FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", as well as "IEC 62304:2006/AC: 2015 - Medical Device Software - Software Lifecycle Processes".

The performance of the device has been evaluated on a retrospective dataset from multiple centers. A summary of the performance data is provided below:

- **Performance of the segmentation of B-mode carotid ultrasound images and measurement of intima-media thickness (IMT):** The performance of the neural network was evaluated on a retrospective dataset of 205 longitudinal B-mode carotid images that were obtained using commercially available ultrasound systems using commercial linear transducers (including a 12-3 MHz linear transducer, and a 12-5 MHz linear transducer). The performance of the subject device was compared against 2 expert readers' measurements and the reported performance of the predicate device. It was observed that the results of the algorithm is strongly correlated with experts' annotations with IMT correlation coefficient of 0.89 with the average of two experts, while the IMT correlation coefficient between the two experts was 0.86. It was also observed that the results of the subject device outperforms the reported results of the predicate device with reported correlation coefficient of 0.6.

- **Performance of the text recognition algorithm for reading annotations from the images**: The performance of the text recognition algorithm was evaluated on a retrospective vascular ultrasound dataset. The performance was measured separately for reading different types of annotations (such as reading the vessel names or doppler velocities) with different number of test images varying from 783 to 1432 images. The text recognition algorithm had a high accuracy in reading different types of annotation varying from 92% to 96%.

- **Performance of the signal processing algorithm for analysing doppler**

waveforms: The performance of the signal processing algorithm for reading peak systolic velocity (PSV) and end diastolic velocity (EDV) was evaluated against the annotations (i.e. PSV and EDV values) on the images annotated by clinicians at the time of image acquisition. The comparison was done on a dataset of 1117 images where each image contains one EDV and one PSV value annotated on the image. Correlation coefficient and Bland-Altman plots were used to evaluate the performance of the signal processing algorithm. Correlation coefficient of 0.98 and 0.97 was obtained for reading PSV and EDV respectively.

- **Performance of the waveform type classifier on lower limb doppler images**: The performance of the doppler waveform type classifier (monophasic, biphasic, or triphasic) on lower limb images was evaluated on a collection of 150 images that represents the breadth of the use cases observed in the clinical field for classifying the waveform type in lower limb arteries. The performance was evaluated against the annotations (i.e. waveform type) by expert readers. It was observed that the algorithm was in strong agreement with the expert annotations with a 93% overall accuracy in detecting the waveform type.

Based on the performance data as well as the Verification and Validation Results, See-Mode Technologies believes that the subject device is substantially equivalent to the predicate and outperforms regarding the segmentation of B-mode carotid ultrasound images and measurement of intima-media thickness (IMT).

See-mode's risk analysis for AVA was completed, with the hazard risk analysis submitted as part of this application. All the risks identified with the subject device are acceptable and have been reduced as far as possible, in accordance with ISO 14971:2007 Medical devices - Application of risk management to medical devices.

The proposed medical device is considered as a Moderate Level of Concern following FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and the required software documentation per FDA's guidance have been provided as part of the submission.

Conclusions

In terms of user safety, similar devices have been utilized for many years with an excellent record of safety. The software technologies are the same as those in the predicate device and other legally marketed devices, and they are used for similar applications in similar manners. There are no new additional safety concerns raised by these technologies.

Performance of the segmentation of B-mode carotid ultrasound images and measurement of intima-media thickness (IMT) outperformed the predicate device. The text recognition algorithm for reading annotations of images, the signal processing algorithm for analysing doppler waveforms and the waveform type classifier on lower limb doppler images were all strongly correlated with the expert readers' annotations.. The high degree of reliability in performance showcases the safety and efficacy of See-Mode's AVA. Furthermore, risks identified during the risk management process have been mitigated as far as possible and all residuals risks have been deemed acceptable.

The predicate device was cleared based on non-clinical supportive information. Similar non-clinical and the analytical study highlighted, shows that AVA's acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, indications for use, non-clinical performance data, software verification and validation, and risk analysis demonstrates that the subject device is safe and effective and is substantially equivalent to the predicate device that has the same intended use.