September 18, 2020

SentiAR, Inc
Berk Tas
Ceo and President
212 Kingshighway Blvd., Suite 115
Mailbox 28
St. Louis, Missouri 63108

Re: K192890
Trade/Device Name: SentEP system
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 18, 2020

Dear Berk Tas:

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
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)*
K192890

Device Name
SentEP system

Indications for Use *(Describe)*
The SentEP system is intended for use as a medical imaging system that allows the review, analysis, communication, and media interchange of multi-dimensional digital images. It is also intended for intraprocedural use. The SentEP system is designed as an additional visualization modality to assist the clinician. The SentEP system is indicated for use in electrophysiology (EP) procedures to assist the clinician in visualization of the heart electroanatomic data.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

1 SUBMITTER INFORMATION

Date Prepared:	August 7, 2020
Submitter's Name and Address	SentiAR, Inc. 212 N. Kingshighway Blvd., Suite 115 Mailbox 28 St. Louis, MO 63108 Telephone: (314) 499-0552
Contact Person:	Berk Tas, Chief Executive Officer

2 DEVICE INFORMATION

Name of Medical Device	Proprietary Name: SentEP system Common Name: Imaging software system
Device Classification	Classification Name: System, Image Processing Radiological Regulation Name: Picture archiving and communication system Regulation Number: 21 CFR 892.2050 Regulatory Class: Class II Product Code: LLZ Classification Panel: Radiology
Device Description	The SentEP system is an imaging system intended to be used as an adjunct product to assist the clinician in visualization of the heart anatomy during cardiac catheter mapping and ablation procedures. Images are imported from an EAMS (electroanatomic mapping system) and displayed through the SentEP system. As a result, users can view both the 2D EAMS display monitor and the 3D SentEP system display at the same time.

3 PREDICATE/REFERENCE DEVICE INFORMATION

Predicate Device	Ceevra Reveal 2.0 cleared via K173274 on July 10, 2018
Reference Device	Abbott EnSite Velocity System cleared via K130594 on May 3, 2013

4 DEVICE DESCRIPTION

The SentEP system is a medical imaging system which allows for the review, analysis, communication, and media interchange of multi-dimensional digital images. Multi-dimensional images are imported from an Electroanatomic Mapping System (EAMS) which are then displayed by the SentEP system software to assist physicians in the visualization of heart electroanatomic data. The SentEP system Head Mounted Display (HMD) provides a view through, stereoscopic 3D view of the data, allowing the user to see the environment as well as the specific holographic image. The SentEP system software additionally provides a 2D view of the

data on the Data Manager PC / Spectator Display for others not using the HMD. Components of the SentEP system are detailed in the table below.

Component	Function
HMD	Used to display the anatomical hologram with real-time data. Used to provide the Operator with the ability to interact with data and images. The system is compatible with up to 5 HMDs in a single shared session
Data Manager PC/ Spectator Display	Used to coordinate transmission of anatomical and real-time data between EAMS and HMDs and to provide a spectator display.
Enclosure	Used to provide network connectivity to EAMS, Data Manager PC/Spectator Display, and HMD
Cables	Used to provide power and network connectivity to components
Proprietary Software	Used to render the model and provide real-time data within the user interface

An Electrophysiologist (EP) is the intended user of the SentEP system. The EP performs procedures in a cardiac electrophysiology laboratory, which is a sterile operating room located in a hospital or clinic. The SentEP system provides the EP with a mixed reality user interface design displayed through the HMD (a commercially available Microsoft HoloLens installed with proprietary software and provided as a component of the SentEP system). Supporting staff members can view the anatomical model on an additional conventional PC display from the same perspective as the controlling EP, while the controlling EP manipulates the display on the HMD. The SentEP system is a non-patient contacting device and is provided non-sterile.

Manipulation of the current EAMS display requires relaying commands from the EP to a nurse or technician within the EP lab or between the EP lab and control room outside of the EP lab. The SentEP system provides the EP direct visualization and control of the EAMS output. The SentEP system does not provide control of the EAMS directly.

In summary, the SentEP system does not deliver therapy, nor does it intervene with therapy. It is intended to provide users with information to assist the clinician in visualization of the heart electroanatomic data.

5 INDICATIONS FOR USE

The SentEP system is intended for use as a medical imaging system that allows the review, analysis, communication, and media interchange of multi-dimensional digital images. It is also intended for intraprocedural use. The SentEP system is designed as an additional visualization modality to assist the clinician. The SentEP system is indicated for use in electrophysiology (EP) procedures to assist the clinician in visualization of the heart electroanatomic data.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SentEP system has similar intended use and indications for use, principles of operation, and technological characteristics as the legally marketed predicate device.

- Both devices are intended as medical imaging systems that allow the review, analysis, communication, and media interchange of multi-dimensional digital images.

- Both devices support viewing 3D digital images on a head mounted display.
- Both devices are intended for intraprocedural use by healthcare professionals.
- Both devices are provided non-sterile and are not intended to be sterilized.
- Both devices are biocompatible for their intended use.

Differences between the SentEP system and the predicate device have been evaluated for impact to safety and performance. Primary differences between the SentEP system and the predicate device are identified below.

- The SentEP system is intended only for intraprocedural use. The predicate device is intended for both preprocedural and intraprocedural use. The SentEP system intended use is a subset of the predicate device intended use, which does not raise any different questions of safety and effectiveness.
- The source data for the SentEP system is derived from the reference device. The predicate device uses a DICOM protocol to generate the 3D dimensional images. While the proposed and predicate devices use different communication protocols, both the SentEP system and the predicate device offer proprietary software for the same purpose of displaying anatomical image data in 3D format, and therefore do not raise any different questions of safety and effectiveness.
- The SentEP system processes streaming live data (dynamic) collected in real-time. The predicate device can process either historical static images or historical dynamic recordings. Both devices process dynamic images that provide the ability to view the data for the intended purpose of each of the devices, and therefore the difference does not raise any different questions of safety and effectiveness.

Although the SentEP system and the predicate device technological characteristics differ in the preprocedural use, communication source, and image data format, performance testing has demonstrated that the SentEP system is as safe and effective as the predicate and that the differences do not raise any different questions concerning safety and effectiveness. The implemented design controls, risk management activities, labeling, and performed verification and validation tests demonstrate the safety and performance of the SentEP system. Based on the comparison information provided above, it is concluded that the SentEP system is substantially equivalent to the predicate device.

7 PERFORMANCE DATA

Verification and validation testing data summarized below were provided in support of the substantial equivalence determination.

Non-Clinical Performance Testing:

Non-clinical performance testing included an evaluation of biocompatibility, mechanical testing, electromagnetic compatibility and electrical safety, wireless capability, and human factors testing.

The safety and performance of the SentEP system have been evaluated and verified according to the specified standards. Verification and validation testing have demonstrated compliance to the software specifications and performance standards. The SentEP system demonstrates conformance specifically to:

- IEC 62304:2006/AC: 2008- Medical device software – Software life cycle processes
- IEC 60601-1:2005 Ed.3+C1; C2 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2 ed 4.0 (2014-02) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Clinical Study:

A clinical study was completed to assess SentEP system usability and performance during EP procedures. The clinical study was a prospective, acute, single center study of 16 pediatric EP patients representing the intended patient population (age 7.3-19.4, 6 males-10 females, 3 ethnicities represented). The study was performed in the United States.

The purpose of this study was to evaluate both the navigational capability of the SentEP system when compared to the EAMS system and the usability of the SentEP system by assessing the user comfort of the device. EP procedures were performed in accordance with normal standard of care for the condition being treated. For a portion of the procedure, the operator had the electroanatomic imaging information displayed on the SentEP system HMD in addition to the traditional EAMS system display while navigating to intended targets.

The equivalency between the SentEP system and the EAMS system was evaluated by comparing: 1) the ability to navigate to 5 locations within allocated time (60s per location), 2) point location accuracy and 3) Physician Exit Survey responses. No adverse events were reported during this study. The comparison of the performance data and safety data collected support the conclusion that the SentEP system was found to have a safety and effectiveness profile that is similar to the legally marketed EAMS system.

8 Safety and Performance Conclusion

Non-clinical and clinical performance testing demonstrated that the SentEP system is as safe and effective as the legally marketed predicate and reference devices. Based on evidence submitted in this premarket notification, including similarities in the indications for use, technological characteristics, and performance between the SentEP system and the predicate and reference devices, the SentEP system raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.