July 14, 2023

SentiAR, Inc.
Alexander Schreiner
Vice President, Quality and Regulatory Affairs
212 N Kingshighway Blvd., Suite 115 Mailbox 28
St. Louis, Missouri 63108

Re: K223290
Trade/Device Name: CommandEP Data Manager PC (DPC02), CommandEP HMD (HMD02)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 13, 2023
Received: June 13, 2023

Dear Alexander Schreiner:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223290

Device Name
CommandEP Data Manager PC (DPC02);
CommandEP HMD (HMD02)

Indications for Use *(Describe)*
CommandEP 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. CommandEP is designed as an additional visualization modality to assist the clinician. CommandEP 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.

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"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 CONTACT DETAILS

Date Prepared	July 9, 2023
Applicant Name	SentiAR, Inc.
Applicant Address	212 N Kingshighway Blvd., Suite 115 Mailbox 28 St. Louis MO 63108 United States
Applicant Contact Telephone	(314) 499-0552
Applicant Contact	Alex Schreiner, Vice President of Quality and Regulatory Affairs

2 DEVICE NAME

Device Trade Name	CommandEP • Data Manager PC (DPC02) • HMD (HMD02)
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

3 LEGALLY MARKETED PREDICATE DEVICE

Predicate #	Predicate Trade Name	Product Code
K192890	SentEP	LLZ

4 DEVICE DESCRIPTION SUMMARY

The SentiAR CommandEP device is a medical imaging system which allows for the review, analysis, communication, and media interchange of multi-dimensional digital images. CommandEP HMD provides a real-time, three-dimensional (3D) visualization of electroanatomic mapping system (EAMS) data (the Mixed Reality (MXR) EAMS Visualization). CommandEP is intended to be used as an adjunct device to assist the clinician in visualization of the cardiac electroanatomic data during cardiac electrophysiology procedures.

Real-time multi-dimensional images are received from an Electroanatomic Mapping System (EAMS) by the touchscreen, all-in-one computer (the Model DPC02 Data Manager PC) and wirelessly transmitted to up to five (5) Head Mounted Displays (the Model HMD02 CommandEP HMD). Additional HMDs may be allocated to facilitate charging and device management. The EAMS is directly connected to the CommandEP by a wired network cable. The CommandEP Data Manager PC communicates with the CommandEP HMDs through a dedicated, encrypted Wi-Fi network provided by the Data Manager PC.

Clinician users view the MXR EAMS Visualization in stereoscopic 3D using optical see-through (OST) HMDs and manipulate the MXR EAMS Visualization using hands-free gaze-dwell controls. The OST display enables clinicians to view both the conventional EAMS display and the CommandEP MXR EAMS Visualization during the procedure. The hands-free controls enable clinicians to control the device without breaking sterility and may also reduce the need to verbalize commands to a non-sterile EAMS technician.

CommandEP allows a clinician user to modify the personal view of data, but does not deliver therapy, intervene with therapy, assist the clinician with therapeutic decisions, or otherwise affect the performance of any other medical device.

CommandEP also provides a shared view function which allows observers or supporting staff to view the cardiac electroanatomic data, with the notated perspective of a selected HMD user, on an either 1) an HMD or 2) a conventional PC display provided by the Data Manager PC (the Spectator Display) to facilitate team communication.

The intended physician user of the CommandEP device is an electrophysiologist. The electrophysiologist performs procedures in a cardiac electrophysiology laboratory, which is a sterile professional healthcare environment. All components of the CommandEP device are non-patient contacting device and are provided non-sterile.

5 INTENDED USE/INDICATIONS FOR USE

CommandEP 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. CommandEP is designed as an additional visualization modality to assist the clinician. CommandEP indicated for use in electrophysiology (EP) procedures to assist the clinician in visualization of the heart electroanatomic data.

6 INDICATIONS FOR USE COMPARISON

The CommandEP indications for use are identical to those of the predicate device.

7 TECHNOLOGICAL COMPARISON

CommandEP has identical intended use and indications for use, principles of operation 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 facilitate 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 CommandEP and the predicate device have been evaluated for impact to safety and performance. Primary differences between CommandEP and the predicate device are identified below.

- CommandEP incorporates compatibility with a different EAMS application programming interface (API), the *CARTO® 3 EP Navigation System Version 7.2* (K213264), which uses a different multi-dimensional image data format. The CommandEP system intended use is identical to the predicate device; there are no different questions of safety and effectiveness.

- CommandEP incorporates a different commercially available computing platform for the HMD. The CommandEP system safety and performance requirements are equivalent to the predicate device; there are no different questions of safety and effectiveness.
- CommandEP integrates an access point in place of a separate physical access point component. The CommandEP system safety and performance requirements are equivalent to the predicate device; there are no different questions of safety and effectiveness.

Other changes which are implemented via documentation include:

- Modification of HMD shared view interface
- Modification of HMD orientation indicator
- Modification of error dialogs

Although CommandEP and the predicate device technological characteristics differ in image data format and HMD computing platform, performance testing has demonstrated that CommandEP 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 CommandEP. Based on the comparison information provided above, it is concluded that CommandEP is substantially equivalent to the predicate device.

8 NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Verification and validation testing data summarized below were provided in support of the substantial equivalence determination. The test methods and acceptance criteria were equivalent to the predicate device in support of the intended use.

Non-clinical performance testing included an evaluation of performance; biocompatibility; electromagnetic compatibility; wireless capability; electrical, mechanical, and thermal safety; and design validation testing.

The safety and performance of CommandEP have been evaluated and verified according to the specified standards below. Verification and validation testing have demonstrated compliance to the software specifications and performance and safety standards:

- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Recognition #2-258]
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)] [Recognition #19-46]
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Recognition #19-39]
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software – Software life cycle processes [Recognition #13-79]

- IEC 63145-20-10 Edition 1.0 2019-08 Eyewear display -- Part 20-10: Fundamental measurement methods -- Optical properties [Recognition #8-580]
- IEC 63145-20-20 Edition 1.0 2019-09 Eyewear display -- Part 20-20: Fundamental measurement methods -- Image quality [Recognition #8-581]

No clinical testing was required to develop evidence of substantial equivalence to the predicate device.

Non-clinical performance testing demonstrated that CommandEP 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 CommandEP and the predicate and reference devices, CommandEP raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.