June 8, 2023

Ablacon, Inc.
Frank Rodrigues
VP Quality Assurance & Regulatory Affairs
4800 Wadsworth Blvd. Suite 310
Denver, Colorado 80033

Re: K230008
Trade/Device Name: Ablamap® System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 31, 2022
Received: January 3, 2023

Dear Frank Rodrigues:

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)*
K230008

Device Name
Ablamap® System

Indications for Use *(Describe)*
The Ablamap® System is used to analyze electrogram (EGM) signals and display results in a visual format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.

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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510(k) Summary

Date summary prepared: December 30, 2022

510(k) Submitter/Holder: Ablacon, Inc.
4800 Wadsworth Blvd. Ste 310
Wheat Ridge, CO 80033

Contact: Frank Rodrigues
VP Quality Assurance & Regulatory Affairs
Telephone: 303-955-5763
Fax: 720-390-7541
Email: fr@ablacon.com

Trade Name: Ablamap® System
Common Name: Diagnostic System
Classification Name: Programmable Diagnostic Computer
Classification: Class II
Product Code: DQK
Review Panel: Cardiovascular
Regulation: 21 CFR 870.1425
510(k) Number: K230008

Predicate Device(s):

Trade/Proprietary Name:	Ablamap® Software (Primary)	LabSystem Pro™ EP Recording System (Secondary)
Common/Usual Name:	Diagnostic Computer	Diagnostic Computer
Classification Name:	Programmable Diagnostic Computer	Programmable Diagnostic Computer
Class:	Class II	Class II
Product Code:	DQK	DQK
Regulation:	21 CFR 870.1425	21 CFR 870.1425
Review Panel:	Cardiovascular	Cardiovascular
510(k) Submitter/Holder:	Ablacon, Inc. 4800 Wadsworth Blvd. Ste 310 Wheat Ridge, CO 80033	Boston Scientific Corp. 55 Technology Dr. Lowell, MA 01851
510(k) #s:	K203084	K141185

Device Description

The Ablacon Ablamap® System is an electrophysiology mapping system used during electrophysiology procedures for assisting in the diagnosis of complex cardiac arrhythmias. The system consists of several hardware elements including an amplifier, cart, monitor, and a workstation with proprietary patented mapping software. Electrogram (EGM) signals are detected by 64-electrode mapping "basket" catheters which are input into, sampled, and amplified by the system's amplifier. The data is transmitted via fiber-optic cable from the amplifier to the workstation and processed by the system's mapping software with the results displayed on the monitor.

The system also accepts EGM data files recorded by EP amplifier recording systems from 64-electrode unipolar "basket" mapping catheters. The EGM data files are electrophysiology (EP) recordings that contain electrogram signals recorded by EP recording systems using 64-electrode "basket" mapping catheters. Compatible EP recording systems are the Boston Scientific LabSystem Pro™, the GE Healthcare CardioLab™ XT, and the St. Jude Medical WorkMate™ Claris System. The recorded EGM data files are saved onto the workstation and processed by the mapping software.

Compatible catheters are 64-electrode mapping "basket" catheters with the following dimensions: 50mm and 60mm sizes; an 8 spline x 8 electrode configuration with nominal electrode spacing of 0.354'' and 0.440" for 50mm and 60mm basket sizes respectively.

Through the software user interface, the user selects to record streamed EGM data from the Ablamap® System signal amplifier that is saved to the workstation or the user selects an EGM data file recorded by an EP Recording System that has been saved to the workstation. The data file is processed by the Ablamap® System software where the EGM signals are converted into electrographic flow® (EGF®) maps indicating flow consistency and direction of the action potential wave propagation during pre-defined time intervals. The resulting EGF® film maps display the flow with respect to the catheter electrodes and show the activity of sources of excitation where action potentials originate.

A Summary Map is displayed that is the graphical representation of the summation of the activity of EGF® sources from all segments of the EGM data file recording indicating the rate of occurrence i.e. prevalence of sources of EGF® with respect to the catheter electrodes.

These graphical maps are evaluated by the physician to assist in the diagnosis of complex cardiac arrhythmias during electrophysiology procedures.

Intended Use

The Ablamap® System is intended to be used during electrophysiology procedures on patients for whom an electrophysiology procedure has been prescribed and only by qualified medical professionals who are trained in electrophysiology.

Indications for Use

The Ablamap® System is used to analyze electrogram (EGM) signals and display results in a visual format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.

Comparative Technological Characteristics

The Ablacon Ablamap® System is an electrophysiological mapping system that uses a proprietary algorithm to process EGM signals and display electrical wave propagation information in a visual

format during pre-defined time intervals. The intended use, indications for use, and fundamental performance are the same as the primary predicate device.

A comparison summary of the technological characteristics of the subject device and the predicate devices are as follows:

Device Characteristic	**Subject Device Ablamap® System (K230008)**	**Predicate Device (Primary) Ablamap® Software (K203084)**	**Predicate Device (Secondary) Boston Scientific LabSystem Pro™ EP Recording System (K141185)** (Clearsign Amplifier component only)
Device Classification, Classification Name, and Product Code	Same	Same	Same
Indications For Use	Used to analyze electrogram (EGM) signals and display results in a visual format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.	Same	A computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.
Intended Use	Intended to be used during electrophysiology procedures on patients for whom an electrophysiology procedure has been prescribed and only by qualified medical professionals who are trained in electrophysiology.	Same	Same
System	Components include an amplifier, cart, monitor, and a computer workstation with Ablamap® mapping software.	Same (excluding amplifier) Stand-alone software may be installed on any commercially available computer meeting minimum performance specifications e.g. a workstation and monitor on a cart.	Amplifier component only

Device Characteristic	Subject Device Ablamap® System (K230008)	Predicate Device (Primary) Ablamap® Software (K203084)	Predicate Device (Secondary) Boston Scientific LabSystem Pro™ EP Recording System (K141185) (Clearsign Amplifier component only)
Compatible Diagnostic Catheters	64-electrode unipolar "basket" mapping catheters; 50mm and 60mm sizes; 8 spline x 8 electrode with nominal electrode spacing of 0.354" and 0.440" for 50mm and 60mm basket sizes respectively.	Same	Same
Compatible EP Recording Systems	Boston Scientific LabSystem Pro™	Same	N/A
	GE Healthcare CardioLab™	Same	N/A
	St. Jude Medical WorkMate™ Claris System	Same	N/A
Signal amplification up to 140 channels	Yes	No	Yes; 40 to 160 channels
Amplifies EGM and ECG signals and transmits to a Workstation	Yes	No	Yes
Signal filter settings -Notch (Power Line) -High-Pass	- Yes - Yes	- No - Same	- Yes - Yes
Signal processing (EGM)	Yes	Same	N/A
Post-processing display	Yes	Same	N/A
Grid display of electrode signals	Yes	Same	N/A
Graphic display view of signal potentials (wave propagation)	Yes	Same	N/A
Method to select and display all time segments of the entire electrogram recording	Yes	Same	N/A
Play/replay animated (film) graphic representation of	Yes	Same	N/A

Device Characteristic	Subject Device Ablamap® System (K230008)	Predicate Device (Primary) Ablamap® Software (K203084)	Predicate Device (Secondary) Boston Scientific LabSystem Pro™ EP Recording System (K141185) (Clearsign Amplifier component only)
signals			
Various display options to assist the user with identification of arrhythmia patterns	Electrical activity Rotational activity Recording timeline Stability/Variability Flow consistency	Same	N/A
Evaluate the quality of the electrogram recording	Yes	Same	N/A
Display the electrogram and electrocardiogram signals (EGM chart including ECG signals)	Yes	Same	N/A
Select and review a time sequence of the signals from various electrodes	Yes	Same	N/A
Programming language	Object-oriented (Python)	Same	N/A
Processing computation method for electrical wave propagation	Optical Flow	Same	N/A
Generate a procedure history file	Yes	Same	N/A
Allow user to add text notes/comments	Yes	Same	N/A
Anatomical location capability	No	No	No

Performance Data

Performance testing was completed on the Ablamap® System which verified that the system meets the specification requirements and performs as designed. The Ablamap® System is suitable for its intended use.

Bench Testing for the subject device included and applied the following standards:

- IEC 60601-1 Ed. 3.1 and applicable Collateral Standards

- IEC 62304 Edition 1.1 2015-06 Medical device software – Software life cycle processes
- ANSI/AAMI/IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer; Part 1: General Requirements

Verification Testing

Verification testing was performed demonstrating the Ablamap® System met design specifications.

Validation Testing

Validation testing was performed demonstrating the Ablamap® System met the user needs and was found to be clinically acceptable by all evaluators.

Usability Testing

Usability testing demonstrated that the Usability Objectives for the Ablamap® System were met with no User Errors observed.

Testing demonstrated that the Ablamap® System met design requirements and functioned as intended.

Conclusion

The data presented in this submission demonstrates that the proposed Ablamap® System operated as intended and is substantially equivalent to the cleared primary predicate device, the Ablamap® Software, and the signal amplifier component of the cleared secondary predicate device, the Boston Scientific LabSystem Pro™ EP Recording System.