August 31, 2021

Ablacon, Inc.
Frank Rodrigues
V.P. of Quality Assurance/Regulatory Affairs
4800 Wadsworth Blvd. Suite 310
Wheat Ridge, Colorado 80033

Re: K203084
Trade/Device Name: Ablamap® Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 20, 2021
Received: July 30, 2021

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 Deoras
Assistant Director (Acting)
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)*
K203084

Device Name
Ablamap® Software

Indications for Use *(Describe)*
The Ablamap® Software 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.

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510(k) Summary per 21 CFR 807.92

Date summary prepared: April 29, 2021

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® Software

Common Name: Diagnostic Software

Classification Name: Programmable Diagnostic Computer

Classification: Class II

Product Code: DQK

Review Panel: Cardiovascular

Regulation: 21 CFR 870.1425

Predicate Device(s):

Trade/Proprietary Name:	**RhythmView™ Workstation**
Common/Usual Name:	Diagnostic Computer
Classification Name:	Programmable Diagnostic Computer
Class:	Class II
Product Code:	DQK
Regulation:	21 CFR 870.1425
Review Panel:	Cardiovascular
510(k) Submitter/Holder:	Abbott Electrophysiology 3668 S. Geyser Road Ste 365 St. Louis, MO 63127
510(k) #s:	K171583

Device Description

The Ablacon Ablamap® Software is a stand-alone software device that uses a proprietary patented algorithm to process electrogram (EGM) signals from data files. The EGM data files are electrophysiology (EP) recordings that contain intra-cardiac electrogram signals recorded by EP recording systems using Abbott Electrophysiology FIRMap™ Catheters, 50mm and 60mm sizes; cleared under 510(k) K163709; a 64-electrode "basket" mapping catheter. The EP recording systems used 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 a computer with the Ablamap® Software installed.

The user selects an EGM data file through the software user interface and the file is processed by the software where the EGM signals are converted into electrographic flow (EGF™) maps indicating relative velocity 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 prevalence 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.

The Ablamap® Software may be installed on any commercially available workstation personal computer (PC) with a Linux Ubuntu 18 LTS operating system and that meets minimum requirements for CPU and GPU processing, random access memory (RAM), and hard drive size.

Intended Use

The Ablamap® Software 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® Software 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® Software is an electrophysiological mapping application 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 predicate device.

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

Device Characteristic	Subject Device Ablamap® Software	Predicate Device Abbott Electrophysiology RhythmView™ Workstation (K171583)
Device classification, Class, and Product code	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
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
System	Stand-alone software that may be installed on any commercially available computer meeting minimum performance specifications.	Fundamentally the same. Workstation cart with software installed on a desktop computer with monitor, keyboard and mouse.
Compatible Diagnostic Catheters	Abbott Electrophysiology FIRMap™ Catheter; 50mm and 60mm sizes	Same
Compatible EP Recording Systems	Boston Scientific (formerly C.R. Bard) LabSystem Pro™	Same
	GE Healthcare (formerly Prucka) CardioLab™	Same
	St. Jude Medical (formerly EP MedSystems) WorkMate™ Claris System	Same
Signal processing	Yes	Yes
Post-processing display	Yes	Yes
Grid display of electrode signals	Yes	Yes
Graphic display view of signal potentials (wave propagation)	Yes	Yes
Method to select and display all time	Yes	Yes

segments of the entire electrogram recording		
Play/replay animated (film) graphic representation of signals	Yes	Yes
Various display options to assist the user with identification of arrhythmia patterns	Electrical activity Rotational activity Recording timeline Variability (Stability)	Same
Evaluate the quality of the electrogram recording exported from the EP recording system	Yes	Yes
Display the electrogram signals (EGM chart)	Yes	Yes
Select and review a time sequence of the electrogram signals from various electrodes	Yes	Yes
Programming language	Object-oriented (Python)	Fundamentally the same. Object-oriented (C++)
Processing computation method for electrical wave propagation	Optical Flow	Phase Angle
Generate a procedure history file	Yes	Yes
Allow user to add text notes/comments	Yes	Yes
Anatomical location capability	No	No

Performance

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

Performance testing for the subject device included the following:

Software design verification and validation testing was performed and complies with:

- 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 14971:2007 Medical devices – Application of risk management to medical devices

The software is considered minor level of concern in accordance with FDA guidelines as a malfunction or failure would not likely contribute to a hazard leading to an injury.

Software usability testing was performed as part of verification and validation testing for functionality and performance.

Testing demonstrated that the software met design requirements and functioned as intended.

Conclusion

The data presented in this submission demonstrates that the proposed Ablacon Ablamap® Software operated as intended and is substantially equivalent to the cleared predicate device, the Abbott Electrophysiology RhythmView™ Workstation.