March 17, 2023

Ablacon, Inc.
% Laurie Lewandowski
VP
Honkanen Consulting, Inc.
738 Saddle Wood Drive
Eagan, Minnesota 55123

Re: K223666
Trade/Device Name: Ablacath™ Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: MTD
Dated: February 16, 2023
Received: February 16, 2023

Dear Laurie Lewandowski:

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 and Part 809); 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)*
K223666

Device Name
Ablacath™ Mapping Catheter

Indications for Use *(Describe)*
For use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Ablacon Ablacath™ Mapping Catheter may also be used for delivery of externally generated pacing stimuli.

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 – K223666

1. SUBMITTER INFORMATION

Submitter:
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DATE PREPARED:
December 07, 2022

2. DEVICE INFORMATION

Proprietary Name:	**Ablacath™ Mapping Catheter**
Regulation Number:	21 CFR 870.1220
Regulation Name:	Electrode Recording Catheter or Electrode Recording Probe
Common/Usual Name:	Catheter, Intracardiac Mapping, High-Density Array
Regulatory Class:	Class II
Product Code:	MTD

3. PREDICATE DEVICE INFORMATION

Proprietary Name:	FIRMap® Catheter
Regulation Number:	21 CFR 870.1220
Regulation Name:	Electrode Recording Catheter or Electrode Recording Probe
Common/Usual Name:	Catheter, Intracardiac Mapping, High-Density Array
Regulatory Class:	Class II
Product Code:	MTD
510K Number:	K163709

4. DEVICE DESCRIPTION

The Ablacath™ Mapping Catheter is a sterile, single use device used to detect electrical potentials from the endocardial surfaces of the heart. They may also be used to deliver

externally generated pacing stimuli. These signals may be used for analysis with a 3-D mapping system.

The catheter's distal end is an expandable basket with eight (8) longitudinal splines each having eight (8) electrodes spaced equal distance along the length of the spline. When expanded it forms a spherical or basket shape. An integrated Introducer Tool collapses the basket for insertion into an 8.5 F sheath. The Ablacath Mapping Catheters are available in two (2) model numbers representing two (2) basket sizes.

- AB-0003-50 is the 50 mm basket size
- AB-0003-60 is the 60 mm basket size

5. INDICATION FOR USE

For use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Ablacon Ablacath™ Mapping Catheter may also be used for delivery of externally generated pacing stimuli.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Ablacath Mapping Catheters have similar technological characteristics as the predicate, Abbott FIRMap Catheter, cleared under K163709. The subject and predicate device both are used for intracardiac electrophysiology mapping and pacing.

A comparison of the Ablacath Mapping Catheter and the FIRMap Catheter is in the following table.

Attribute / Device Characteristics	Proposed Device Ablacath™ Mapping Catheter	FIRMap® Catheter K163709 Predicate
Intended Use	Intracardiac electrophysiology mapping and pacing	Identical
Indications for use	For use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Ablacon Ablacath™ Mapping Catheter may also be used for delivery of externally generated pacing stimuli.	For use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The FIRMap Catheter may also be used for delivery of externally generated pacing stimuli.
Users	Electrophysiologists	Identical
Device Components	Basket	Identical

Attribute / Device Characteristics	Proposed Device Ablacath™ Mapping Catheter	FIRMap® Catheter K163709 Predicate
	Shaft Handle Introducer Tool	
Basket Dimensions	50 mm 60 mm	50 mm 60 mm 70 mm
Catheter Shaft Diameter	2.8 mm	Identical
Length	128± 1cm	Identical
Effective Length	113 cm	Identical
Recommended Guide Sheath Size	8.5F	Identical
Number of Splines	8 (expanding)	Identical
Strut Material	Nitinol	Identical
Spine Tube Material	Pebax	Identical
Catheter Tubing	Pebax	Identical
Number of Electrodes	64	Identical
Electrode Material	Gold Plated Copper	Identical
Electrode Configuration	Unipolar or Bipolar	Identical
Electrical Rating	Maximum = ±30 V, 25 mA	Typical = ±27 V, 25 mA
Dielectric Strength	500 VDC	500 VDC
Sterility	EO sterilized	Identical
SAL	$1x10^{-6}$	Identical
Biocompatible	Yes	Identical

The Ablacath Mapping Catheter has the same intended use and indications for use as the predicate. The technological characteristics are similar to the predicate. The difference electrical rating reflects the actual testing performed on the subject device. The Ablacath Mapping Catheter is substantially equivalent to the predicate device.

7. PERFORMANCE DATA

Bench Testing

All testing was performed pre and post aging (per ASTM F1980:2016), except for radiopacity and electrical safety testing, that were performed at T=0.

- Visual / Dimensional

- Mechanical Integrity– flexibility, kink, spline radial strength, basket vertical compression Flexibility
- Torque Resistance / Strength
- Track Force/Withdrawal Cycling and Withdrawal Force
- Radiopacity per ASTM F640
- Corrosion per ISO 10555-1
- Fluid Leak
- Mating / Uncoupling Force
- Tensile Testing per ISO 10555-1
- Continuity / resistance / pin short, spline orientation, and connector alignment
- Electrical Safety Testing per ISO 60601-1

Packaging

- Distribution per ASTM D4169:2016
- Environmental Conditioning per ISTA 3A:2011
- Aging per ASTM F1980:2016
- Packaging per ISO 11607-1:2006
  - Visual per ASTM F1886-16/F1886M-16
  - Bubble Leak per ASTM F2096-11:2019
  - Seal Strength per ASTM F88/F88M-15

All tests met the predefined acceptance criteria. The test results demonstrated that differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.

Summary of Pre-clinical Studies

Preclinical animal studies were performed to confirm validation and usability requirements using a swine model under simulated use conditions. The studies complied with the guidelines for nonclinical laboratory studies as described in CFR 21 Part 58.

- GLP Validation Testing

  The purpose of the study was to ensure that Ablacath Mapping Catheter conformed to the intended user needs and indication for use through the evaluation of each performance requirement and met acute safety attributes as evaluated by physician end-users. The Ablacath Mapping Catheter met all study endpoints; performance and acute safety requirements and was found to be clinically acceptable by all evaluators with the performance equivalent to the predicate device.

- GLP Usability Testing

  The purpose of the study was to obtain performance data through observation of the end-users under simulated end-use environment. No User Errors or Close Calls were observed in any of the physician end-users in the conduct of the usability validation study.

Biocompatibility

Biocompatibility testing was performed in accordance with:

- ISO 10993-1:2018 for a limited (<24 hour), externally communicating, circulating blood contacting device
- Chemical Characterization per ISO 10993-18:2020
- Cytotoxicity: MEM Extraction Cytotoxicity Assay per ISO 10993-5:2009
- Sensitization: Guinea Pig Maximization Test per ISO 10993-10:2010
- Irritation: Intracutaneous Reactivity Test, per ISO10993-10:2010
- Toxicity: Acute Systemic Toxicity per ISO 10993-11:2017
- Toxicity: Materials Medicated Rabbit Pyrogen Test ISO 10993-11:2017
- Hemocompatibility: Hemolysis Direct and Indirect per ISO 10993-4: 2017
- Hemocompatibility: C3a and SC5b-9 Complement Activation ISO 10993-4: 2017
- Hemocompatibility: In Vivo Thromboresistance ISO 10993-4: 2017

All devices met their endpoints.

Sterilization:

Sterilization (ethylene oxide) and packaging of the Ablacath Mapping Catheter were validated using the following standards:

- ANSI/AAMI/ISO 11135-1:2014 Sterilization of health-care products – ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices

Testing demonstrated that all endpoints were met.

8. CONCLUSION

The Ablacath Mapping Catheter is substantially equivalent in terms of the intended use, indications for use, technological characteristic, performance testing and comparison to the cited predicate, and does not present any new questions of safety and effectiveness.