June 14, 2019

Catheter Precision, Inc.
Karen Bannick
Regulatory Affairs Consultant
500 International Drive
Suite 333
Mt. Olive, New Jersey 07828

Re: K183195
Trade/Device Name: VIVO
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 9, 2019
Received: May 15, 2019

Dear Karen Bannick:

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)*
K183195

Device Name
VIVO

Indications for Use *(Describe)*

VIVO is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

VIVO is intended to be used as a pre-procedure planning tool for patients with structurally normal hearts undergoing ablation treatment for idiopathic ventricular 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.

Catheter Precision

Applicant's Name	Catheter Precision, Inc. (Owner/Operator) 500 International Drive Suite 333 Mt. Olive, NJ 07828 Telephone: (973) 691-2000 **Establishment Registration No:** 3010728615
Primary Contact:	Mr. Steve Adler Chief Executive Officer Telephone: (973) 691-2000 Email: steve.adler@catheterprecision.com
Alternate Contact:	Ms. Karen Bannick Regulatory Affairs Consultant Bannick Consulting, LLC Telephone: (320) 630-5171 Email: Karen@bannickconsulting.com
Trade Name:	VIVO™
Common Name:	Electrophysiological cardiac mapping system
Classification Name:	Programmable diagnostic computer
Date Revised:	June 13, 2019
Classification/Panel:	Class II, Cardiovascular
Product Code:	DQK

Regulation Number: 21 CFR 870.1425

Predicate Device: Medtronic CardioInsight® Cardiac Mapping System (K162440)

Device Description:

The VIVO system is a noninvasive pre-procedure planning tool that provides a 3D mapping of the heart to aid in the identification of the general location of the origin of focal ventricular arrhythmias prior to electrophysiology procedures. VIVO requires acquisition of MRI or CT images and standard ECG recordings and lead (electrode) placement. Electrocardiographic potentials are measured from the torso using standard 12 lead electrocardiogram (ECG) sensors placed on the surface of the body. A DICOM image (CT or MR scan) of the thorax and heart is acquired and then segmented to provide a detailed, three-dimensional (3D) anatomy of the endocardial and epicardial surface of the heart. A 3D photograph of the patient's chest with the precise ECG lead positions used to acquire the 12 lead ECG is merged with the torso and heart model to determine the spatial relationship between the electrodes and the heart. From these data, the system uses a mathematical algorithm to use the geometrical information to transform the measured body surface potentials into myocardial potentials via solving the cardiac inverse problem. The VIVO system uses an off the shelf laptop computer and a handheld 3D camera. The VIVO software creates, displays, and stores a cardiac model that displays the site of earliest activation of ventricular arrhythmias.

To develop the cardiac model, VIVO requires the following inputs:

- MR or CT scan images in the DICOM file format are imported and combined with preloaded reference models in the VIVO software
- Standard 12-lead ECG recordings acquired during the arrhythmia are imported to VIVO software
- A 3D photograph of the placement of the ECG leads is created using the VIVO 3D camera

VIVO software is comprised of two software applications, VIVO Anatomy and VIVO Analysis.

VIVO Anatomy merges the imported cardiac MR/CT image data with a model to create a heart and torso model representative of a patient's specific anatomy. The MR/CT image data must be imported via a DVD containing the images in DICOM format (Note: VIVO does not have a web interface). The DICOM image is then overlayed on top of one of a number of preloaded anatomical models to fine tune the preloaded model. The model that best matches the patient's anatomical profile is chosen. Specific cardiac structures and tissues are identified by the User within the images to better match the patient anatomy. An outline of the chambers and tissue walls is automatically created by VIVO which is then finetuned by the User for a precise match to the patient's anatomy.

VIVO Analysis combines the heart and torso model generated from VIVO Anatomy with ECG data, and a 3D photograph of the ECG lead placement to identify the location of the arrhythmia foci. After ECG leads are placed on the patient, a 3D photograph of the patient's chest is captured to accurately record lead locations. Arrhythmic ECG signals are recorded from these electrodes and imported into the VIVO software. This data is combined and a mathematical algorithm is used create a 3D rendering of the patient's heart with superimposed color coding to indicate the area of earliest activation.

Model Number of VIVO System: 9001.

Comparison of Technical Characteristics with Predicate Device

This submission is seeking the clearance of the VIVO system which, like the predicate device, provides a 3D mapping of the heart to aid in the identification of the general location of the origin of focal cardiac arrhythmias prior to electrophysiology procedures.

The predicate device and the VIVO system have the same intended use, fundamental technology, principal of operation and performance. Both VIVO and the predicate require a DICOM image and location data of the electrodes to create a patient specific model.
VIVO users review and adjust a merged 3D image of the 12 lead ECG electrode locations and the torso. Users of the predicate add and delete electrodes after the algorithm merges ECG location with the torso using a segmentation process.

Where there are technological differences, they do not affect the safety and effectiveness of the device when used as labeled. Table 1 provides a comparison of the technological characteristics for the VIVO system against the predicate device.

Table 1: Technological Characteristics Comparison

Characteristic	VIVO™ Subject Device	Medtronic CardioInsight™ K162440	Rationale for Differences (if applicable)
Product Code	DQK	DQK	Same
Regulation	21 CFR 870.1425	21 CFR 870.1425	Same
Intended Use	For individuals undergoing an EP study for focal ventricular arrhythmias.	For individuals undergoing an EP study.	VIVO software has not been validated for atrial use.
Indications for Use	VIVO is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician. VIVO is intended to be used as a pre-procedure planning tool for patients with structurally normal hearts undergoing ablation treatment for idiopathic ventricular arrhythmias.	The Medtronic CardioInsight Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.	
System	Monitor, Core Processor, Keyboard, and Mouse (all part of the laptop computer), 3D Camera (Kinect™).	Cart, Monitor, Core Processor, Keyboard, Mouse, Isolation Transformer, Cabling, Sensor Array, Second Monitor connection.	
DICOM Compliance	Yes	Yes	Same

Image Scan Modalities Accepted	CT, MR	CT	
Principles of Operation	Electrocardiographic potentials are measured from standard 12-lead ECG. VIVO establishes patient torso geometry via segmented DICOM images and ECG electrode placement via a 3D photograph. From these data, the system uses mathematical algorithms to use the geometrical information to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem.	Electrocardiographic potentials are measured from the torso sensors on the surface of the body. A CT scan is segmented to obtain the 3- dimensional location of each sensor and the detailed anatomy of the epicardial surface of the heart. From these data, the system uses mathematical algorithms to use the geometrical information to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem.	
Functional Overview	Basic Steps to Mapping: 1. MR/CT images are imported and used to build 3D model of the patient's heart and torso 2. Overlay ECG location via 3D camera 3. Align torso/heart model 4. Load ECG Data 5. Analyze 6. Produce map	Basic Steps to Mapping: 1. CT images are imported and used to build 3D model of the patient's heart 2. Capture 3D geometry of patient's torso (from vest) 3. Overlay ECG location during CT image acquisition	The method of generating the map does not impact the final results.

		4. Align torso/heart model 5. Load ECG data 6. Analyze 7. Produce map	
ECG Acquisition ECG Electrode Identification/ Localization	Standard 12-lead surface ECG output imported into VIVO device Standard 12 lead ECG electrode locations acquired with 3D imaging camera. Algorithm merges the 3D image of the 12 lead ECG electrode locations with torso. User manually adjusts the electrode position to the 3D image for accuracy.	Proprietary vest with 252 electrodes for surface ECG and recorded through proprietary ECG acquisition hardware/firmware Custom 252 electrode images acquired during CT imaging. Algorithm merges ECG location with torso with a segmentation process. User manually adds and deletes electrodes after merge.	VIVO uses a standard 12-lead ECG and standard lead placement. VIVO captures the lead locations relative to the patient's torso geometry using the Kinect 3D camera to obtain a 3D photograph. The predicate, CardioInsight utilizes a 252 electrode sensor-array vest to gather the ECG and determine the patient's torso geometry.
Cardiac Maps Provided	Color coded map of earliest activation point and propagation of cardiac beat	Activation map, directional activation map, phase map, potential map, voltage map, slew rate map, propagation map	VIVO's color coded activation map is provided for illustrative purposes only during pre-procedure mapping.

Indications for Use:

VIVO is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

VIVO is intended to be used as a pre-procedure planning tool for patients with structurally normal hearts undergoing ablation treatment for idiopathic ventricular arrhythmias.

Performance Data

Performance testing was completed on the VIVO system which verified that the device complies with the safety and specifications and performs as designed. VIVO is suitable for its intended use. Performance Testing included hardware testing, software verification and integration testing performed in compliance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and AAMI / ANSI / IEC 62304:2006, Medical Device Software - Software Life Cycle Processes, clinical testing, system verification and validation testing for functionality and performance in a simulated environment.

Clinical Study

A prospective, non-randomized study ("VIVO Accuracy Study") was completed at 6 US centers. This clinical evaluation was developed primarily to assess VIVO's ability to accurately determine the anatomical location of a particular ventricular origin. The VIVO Accuracy Study enrolled 51 patients and analyzed data from 45 patients presenting for PVC or VT ablation with structurally normal hearts and less than 10% scar.

Approximately 47% of subjects were male, and the average age was 56.4 years. Of the 45 subjects, 44 underwent an ablation procedure for PVCs and 1 underwent an ablation procedure for ventricular tachycardia (determined day of procedure). There was no subgroup analysis conducted.

Of the 45 subjects, 20% (N=9) had previous ablations and no subjects had a previous myocardial infarction (MI). Other arrhythmias were noted at baseline in 53.33% (24), and 15.56% (N=7) reported having no symptoms associated with their PVC or VT. The most common symptom was palpitations which was reported in 57.78% (N=26) of subjects.

The study results demonstrated acceptable clinical accuracy performance of VIVO. There were no adverse events. The primary endpoint assessed the accuracy of VIVO to properly identify a PVC or VT foci in the right, left, or septal region of the heart. It was determined that the VIVO localization of the PVC/VT foci agreed (was a match) with the CARTO localization in 45 of the 45 subjects. Thus, the primary endpoint had an accuracy rate of 100% (95% CI: 93.6%, 100%), which met the pre-specified performance goal.

Conclusion
The data presented in this submission demonstrate that the VIVO system is substantially equivalent to the predicate device identified in intended use, device design, fundamental technology and performance.