September 14, 2020

Catheter Precision, Inc.
Steve Adler
CEO
500 International Drive, Suite 255
Mt. Olive, New Jersey 07828

Re: K200313
Trade/Device Name: VIVO™
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 30, 2020
Received: August 5, 2020

Dear Steve Adler:

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
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)*
K200313

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.

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5. 510(k) Summary

Applicant's Name	Catheter Precision, Inc. (Owner/Operator) 500 International Drive, Suite 255 Mt Olive, NJ 07828 USA 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 McQuoid Regulatory Affairs Consultant Bannick, LLC Telephone: (612) 310-4529 Email: karen@bannickprimary.com
Trade Name:	VIVO™
Common Name:	Electrophysiological cardiac mapping system
Classification Name:	Programmable diagnostic computer
Date Prepared:	
Classification/Panel:	Class II, Cardiovascular
Product Code:	DQK
Regulation Number:	21 CFR 870.1425
Predicate Device:	Catheter Precision VIVO™ (K183195)

Device Description:

The VIVO system is a noninvasive pre-procedure planning tool that provides a 3D mapping of the heart to aid in identifying the origin of cardiac arrhythmias prior to electrophysiology procedures. VIVO requires acquisition of MRI or CT images combined with standard ECG recordings and electrode placement. Electrocardiographic potentials are measured from the torso using standard 12 lead electrocardiogram (ECG) electrodes 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 patient specific, three-dimensional (3D) anatomy of the endocardial and epicardial surfaces of the heart. A 3D photograph of the patient's chest with the precise ECG lead locations and positioning patches that were used to acquire the ECG is merged with the torso and heart model to determine the spatial relationship between them. From these data, the system uses a mathematical algorithm to assimilate the geometrical information and transform the measured body surface signals into epicardial signals by solving the cardiac inverse problem. VIVO software creates, displays, and stores a cardiac activation map that displays the site of earliest activation of ventricular arrhythmias.

The VIVO system includes an off the shelf laptop computer and a handheld 3D camera. The preloaded software takes data from previously acquired cardiac and thoracic images, standard 12-lead ECG recording made during an arrhythmia and 3D picture of the placement of the ECG leads and positioning patches. This information, obtained prior to the procedure, can be used during pre-procedure planning by a qualified physician.

Model Number of VIVO System: 9002.

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.

Comparison of Technical Characteristics with Predicate Device

This submission is seeking the clearance of the VIVO Model 9002 system which, like the predicate device the VIVO Model 9001, 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 VIVO Model 9002 system has the same intended use, fundamental technology, principles of operation and performance as the predicate device. Where there are minor technological differences, they do not affect procedure, how the device is used, performance, function or safety compared to the predicate. Two changes include a smaller camera and the inclusion of positioning patches. VIVO Model 9002 includes an improved Graphical Use Interface (GUI) workflow during the Anatomy, 3D Image and

ECG functions; however, the Analysis algorithm is identical to VIVO Model 9001. The fundamental Analysis algorithm creates, displays and stores a cardiac activation map that identifies the localization of the earliest activation of an arrhythmic heartbeat.

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™ Model 9002**	**VIVO™ Model 9001**	**Rationale for Differences (if applicable)**
	Subject Device	K183195	
Product Code	DQK	DQK	Identical
Regulation	21 CFR 870.1425	21 CFR 870.1425	Identical
Intended Use	For individuals undergoing an EP study for ventricular arrhythmias.	For individuals undergoing an EP study for ventricular arrhythmias.	Identical
Indications for Use	VIVO is intended for the acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.	VIVO is intended for the acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.	Identical
System Components	Monitor, Core Processor, Keyboard, and Mouse (all part of the laptop computer), positioning patches.	Monitor, Core Processor, Keyboard, and Mouse (all part of the laptop computer).	Minor Technical Difference: Positioning patches are included in the 3D Image.
3D Camera	3D Camera (Intel® RealSense™),	3D Camera (Kinect™).	Minor Technical Difference: The 3D camera has been replaced with a smaller camera. Output images used by VIVO are equivalent.
Manufacturer	Intel	Microsoft	
RGB Camera resolution (pixels)	1920 x 1080	1920 x 1080	
Frame rate (fps)	30	30	
Depth Camera resolution (pixels)	1280 x 720	512 x 424	
Frame rate (fps)	90	30	
Color field of view: horiz/vert (degrees)	74 x 62	70 x 60	

Characteristic	**VIVO™ Model 9002**	**VIVO™ Model 9001**	**Rationale for Differences (if applicable)**
Connector	USB 3.1 type C	USB 2.0 type A	
Size (mm)	90 x 25 x 25	249 x 66 x 67	
Weight	0.6 oz	3.1 lbs.	
Graphical User Interface	Functions are on display, dialog boxes and pop-up messages, sliders, menus structure for simplification and improved workflow	Many functions require use of mouse/key shortcuts	Minor Technical Differences: Changes with VIVO Model 9002 simplify the user interface.
DICOM Compliance	Yes	Yes	Identical
Image Scan Modalities Accepted	CT, MR	CT, MR	Identical
Principles of Operation	Electrocardiographic potentials are measured from the torso electrodes on the surface of the body. A CT or MRI scan is segmented to obtain the detailed anatomy of the epicardial and endocardial surface of the heart and torso geometry. The exact location of the ECG leads to the heart are then identified within the software. 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 electrodes on the surface of the body. A CT or MRI scan is segmented to obtain the detailed anatomy of the epicardial and endocardial surface of the heart and torso geometry. The exact location of the ECG leads to the heart are then identified within the software. 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.	Minor Technical Differences: VIVO Model 9002 establishes patient torso geometry via semi-automated segmentation or manual DICOM images compared to manual with VIVO Model 9001. VIVO Model 9002 has eight 3-D models compared to 2 with VIVO Model 9001
Functional Overview	Steps to Mapping: 1. MR/CT images are imported and used to build 3D model	Steps to Mapping: 1. MR/CT images are imported and used to build 3D model	Minor Technical Difference: Positioning patches facilitate merging of the 3D image and heart/torso model.

Characteristic	**VIVO™ Model 9002**	**VIVO™ Model 9001**	**Rationale for Differences (if applicable)**
	of the patient's heart and torso 2. Overlay ECG and positioning patch location via 3D camera 3. Align torso/heart model 4. Load ECG Data 5. Analyze 6. Produce map	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	
Software / Firmware / Algorithm	• Create patient records • Segment heart and electrodes • Acquire ECG data • Create and review maps	• Create patient records • Segment heart and electrodes • Acquire ECG data • Create and review maps	Minor Technical Differences: Simplified clinical workflow, combined two software applications into one, and improved user interface.
ECG Compatible Formats	Expanded ECG formats: mat, UNI, XML, inf, zip, csv, txt	inf, and mat (Bard conversion)	Minor Technical Difference: VIVO Model 9002 allows additional ECG formats.
Report Generation	PNG image as screen shot, and VTK export	None	Minor Technical Difference: VIVO Model 9002 has added a report generation function which can be created and exported.

Performance Data

Performance testing was completed on the VIVO Model 9002 system in the same manner as the predicate device. Performance testing, adapted where necessary to evaluate minor technical changes, included product system 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, system verification and validation testing for functionality and performance in a simulated environment.

Testing included:

Performance Testing
System Testing to verify that the device met system requirements and the component operation and performance. The testing included the assembled VIVO Model 9002 device met the specified requirements. This included the accessing the VIVO software, Laptop PC function and 3D camera function (with positioning patches). Conclusion: System performance specifications were successfully verified to meet design outputs at the end of the bench testing.

Bench testing was performed to confirm the ability of the system to collect the position of the patches and electrodes.

User Validation Testing was conducted to address the use related risks associated with using/navigating the software and successful rendering of an accurate image; in particular to evaluate the usability of the new software workflow and the User's ability to generate a 3D model. Critical and essential tasks were identified and data collected included task performance (pass, fail, close call/serious difficulty), with pass/fail criteria clearly defined. Conclusion: The user validation testing supporting the accuracy of the user to generate a 3D model by the simplified workflow, and that the design has mitigated user error to an acceptable level.

Biocompatibility Testing
Biocompatibility testing was performed to demonstrate that the positioning patches conform to ISO 10993-1. The results demonstrate that the device is biocompatible.

Shelf Life Testing
Shelf life testing was performed to demonstrate a one-year shelf life for the positioning patches.

Clinical Testing
Not required to demonstrate substantial equivalence to the predicate device.

Conclusion of Performance Testing:

Performance testing verified that the VIVO system complies with the safety and specifications and performs as designed. Therefore, VIVO is suitable for its intended use.

Conclusion

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