October 30, 2026

Catheter Precision, Inc.
Darci Diage
Regulatory and Quality Representative
1670 Hwy. 160 W., Suite 205
Fort Mill, South Carolina 29708

Re: K261886
Trade/Device Name: VIVO
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 1, 2026
Received: October 1, 2026

Dear Darci Diage:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See

the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARCO CANNELLA -S

Marco Cannella, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261886

Please provide the device trade name(s).

VIVO

Please provide your Indications for Use below.

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 and for patients with structural heart disease undergoing catheter ablation of monomorphic ventricular tachycardia (VT).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261886

510(k) Summary

Prepared on: 2026-10-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Catheter Precision, Inc
Applicant Address	1670 Highway 160 West Suite 205 Fort Mill SC 29708 United States
Applicant Contact Telephone	7079532615
Applicant Contact	Mrs. Darci Diage
Applicant Contact Email	ddiage@catheterprecision.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VIVO
Common Name	Programmable diagnostic computer
Classification Name	Computer, Diagnostic, Programmable
Regulation Number	870.1425
Product Code(s)	DQK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200313	VIVO	DQK

Device Description Summary

21 CFR 807.92(a)(4)

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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 and for patients with structural heart disease undergoing catheter ablation of monomorphic

ventricular tachycardia (VT).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use for the subject device is updated to remove the restriction to those patients with structurally normal hearts and idiopathic ventricular arrhythmias. The change in indications for use has not changed the intended use because the subject and predicate are both intended as a pre-procedural planning tool.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and predicate device have identical technological characteristics. There have been no modifications to the device since the initial clearance. The VIVO software and positioning patches have not been modified since clearance was obtained in K200313. The VIVO System continues to use consumer electronics accessories as to what was submitted in K200313. The only change to VIVO is the Indications for Use in the labeling.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Clinical Data

Clinical data from two physician-initiated prospectively studies (Al-Sheikhli J et al. Europace 2026 and Misra S et al. Journal of Eelectrocardiology 2018) was used to support the expansion of indication for the device use in patients with structural heart disease undergoing catheter ablation of monomorphic ventricular tachycardia (VT).

The two studies included a total of 39 VT patients of ischemic (n = 24) or non-ischemic (n = 15) etiology with 57 VT morphologies (38 in patients with ischemic cardiomyopathy and 19 in those with non-ischemic cardiomyopathy) to evaluate the accuracy of the VIVO System in localizing the site of earliest ventricular activation during sustained monomorphic VT in patients with structural heart disease.

All VT morphologies were mapped with both the VIVO System and electro-anatomical mapping (EAM). The site of earliest ventricular activation predicted by the VIVO System was analyzed by investigators who were blinded to the results of EAM. The results of VIVO analysis were compared to EAM performed to determine the arrhythmogenic substrate. Myocardial segments were assigned for the VT-exit site/region, critical isthmus, and successful ablation sites using the ventricular American Heart Association segment model.

In patients with ischemic cardiomyopathy, a complete match between VT exit site/region on EAM and earliest site of ventricular activation on VIVO occurred in 25 (65.8%) VT morphologies and a partial match in 9 (23.7%). In patients with non-ischemic cardiomyopathy, a complete match between VT exit site/region on EAM and earliest site of ventricular activation on VIVO occurred in 13 (68.4%) VT morphologies and a partial match in 3 (15.8%).

The results of the physician-initiated studies supported a clinically acceptable performance of the VIVO System in patients with structural heart disease undergoing catheter ablation of monomorphic VT.

Conclusion

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