April 13, 2026

Corify Care S.L
% Shilpa Gampa
Deputy General Manager and US Agent
Freyr, Inc.
150 College Rd. W #102
Princeton, New Jersey 08540

Re: K253861
Trade/Device Name: ACORYS MAPPING SYSTEM
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 18, 2025
Received: December 3, 2025

Dear Shilpa Gampa:

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.

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 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,

MARCO CANNELLA -S

for:

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

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.	K253861

Please provide the device trade name(s).

ACORYS MAPPING SYSTEM

Please provide your Indications for Use below.

The ACORYS MAPPING SYSTEM is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.
The ACORYS MAPPING SYSTEM is indicated for patients with cardiac arrhythmia and/or cardiac electrical disorders.
The ACORYS MAPPING SYSTEM is indicated for use in adults.
The ACORYS MAPPING SYSTEM can be used in regular medical consultations or in Hospitals during cardiac electrophysiological interventions.
The ACORYS MAPPING SYSTEM is indicated for use in intact skin only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253861

corify care

Solving cardiac arrhythmias

510(k) Summary

Device: ACORYS MAPPING SYSTEM

1. Submitter Information

Applicant:

Corify Care S.L.

C/ Doctor Castelo 44 – Bajo Izq., 28009

Madrid (Spain)

Applicant Contact Person:

Javier Milagro

Chief Operations Officer

Corify Care S.L.

C/ Doctor Castelo 44 – Bajo Izq., 28009 Madrid (Spain)

M: +34 910 888 183

javier.milagro@corifycare.com

Application Correspondent:

Shilpa Gampa

Deputy General Manager and US Agent

Freyr Inc

M: +1 760-5834401

usagent@freyrsolutions.com

2. Device Information

Trade Name	**ACORYS MAPPING SYSTEM**
Regulation Number	**21 CFR 870.1425**
Regulation Name	**Programmable Diagnostic Computer**
Regulatory Class	**Class II**
Product Code	**DQK**
510(k) Number	**K253861**

2.1. Device Description

The ACORYS MAPPING SYSTEM (ACORYS) is a non-invasive cardiac mapping system based on electrocardiographic imaging, that provides three-dimensional (3D) electroanatomic maps of the heart. It combines body surface potential measurements with a 3D model of the torso to generate panoramic, bi-atrial and/or bi-ventricular 3D electroanatomic maps.

System components:

The ACORYS MAPPING SYSTEM is comprised of the following components:

1. **ACORYS Sensor Vest (ACSEN):** High density sensor array for the acquisition of surface electrocardiographic signals. ACSEN is a type-CF applied part.
2. **ACORYS Amplifier (ACAMP)**: Module used to amplify and digitalize the signals acquired from the patient's torso. ACAMP includes two extra submodules, ACTRA and ACCABx defined as follows:
   - 2.1. **ACORYS Isolation transformer (ACTRA):** Medical degree isolation transformer to charge the internal batteries of the amplifier.
   - 2.2. **ACORYS Connector Cables (ACCAB_L and ACCAB_R)**: Elements to transmit the electrical signals acquired by the sensor vest to the amplifier. ACCAB_L and ACCAB_R are type CF applied parts.
3. **ACORYS Software (ACSOF):** Software for signal analysis. The results of the said analysis are displayed as electroanatomic maps that allow the evaluation of the electrical activity on the surface of the heart. ACSOF is installed on a workstation that is connected to the amplifier via ACORYS Isolation Ethernet (ACNET), an ethernet isolator 60601 compliant.
4. **ACORYS 3D Scan Software (ACSCAN):** Module for the 3D reconstruction of the patient´s torso.

Additionally, the ACORYS software operates on commercially available general-purpose hardware components provided as part of the system:
Workstation: The ACSOF module operates on a workstation running a compatible which provides the computing environment required for data processing, visualization, and analysis. Standard peripherals such as a monitor, keyboard, and mouse may be used.

3D Scan Platform: The ACSCAN module operates on a tablet-based platform that integrates a compatible 3D sensor for anatomical acquisition. This platform enables 3D torso reconstruction and electrode localization for subsequent processing within the ACORYS system.

Materials:

The ACORYS Mapping System includes hardware components that incorporate materials intended for patient contact and for electrical insulation.

The ACORYS Sensor Vest (ACSEN) includes skin-contacting materials such as adhesive and conductive hydrogels, which are used for signal acquisition. These materials have been evaluated for biocompatibility and are non-cytotoxic, non-irritating, and non-sensitizing.

The ACORYS Amplifier (ACAMP) incorporates materials that ensure appropriate electrical insulation and safe operation of the device, as verified through applicable electrical safety and electromagnetic compatibility testing.

2.2. Indications for Use

The ACORYS MAPPING SYSTEM is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

The ACORYS MAPPING SYSTEM is indicated for patients with cardiac arrhythmia and/or cardiac electrical disorders.

The ACORYS MAPPING SYSTEM is indicated for use in adults.

The ACORYS MAPPING SYSTEM can be used in regular medical consultations or in Hospitals during cardiac electrophysiological interventions.

The ACORYS MAPPING SYSTEM is indicated for use in intact skin only.

2.3. Intended Patient Population / Medical Condition

The ACORYS MAPPING SYSTEM is indicated for patients with cardiac arrhythmia and/or cardiac electrical disorders.

The ACORYS MAPPING SYSTEM is indicated for use in adults.

2.4. Intended users

The ACORYS MAPPING SYSTEM is indicated for being used only by persons trained by or under the guidance of trained Corify Care S.L. personnel.

3. Predicate and reference device

3.1. Primary predicate device

PRIMARY PREDICATE DEVICE	
Product Name	Medtronic CardioInsight™ Cardiac Mapping System
Manufacturer	Medtronic, Inc.
510(k) Number	K162440
Regulation Number	21 CFR 870.1425
Regulation Name	Programmable Diagnostic Computer
Regulatory Class	Class II
Product Code	DQK

3.1. Reference Device

REFERENCE DEVICE	
Product Name	Vektor Computational ECG Mapping System (vMap™)
Manufacturer	Vektor Medical, Inc.
510(k) Number	K211546
Regulation Number	21 CFR 870.1425
Regulation Name	Programmable Diagnostic Computer
Regulatory Class	Class II
Product Code	DQK

4. Substantial equivalence comparison

CHARACTERISTIC	SUBJECT DEVICE (ACORYS MAPPING SYSTEM, K253861)	PRIMARY PREDICATE (MEDTRONIC'S CARDIOINSIGHT, K162440)	REFERENCE DEVICE (VEKTOR'S VMAP, K211546)
Intended use	ACORYS MAPPING SYSTEM is intended for the acquisition, analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.	The Medtronic CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.	The Vektor Computational ECG Mapping System (vMap™) is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.
Indications for use	The ACORYS MAPPING SYSTEM is indicated for patients with cardiac arrhythmia and/or cardiac electrical disorders. The ACORYS MAPPING SYSTEM is indicated for use in adults. The ACORYS MAPPING SYSTEM can be used in regular medical consultations or in Hospitals during cardiac electrophysiological interventions. The ACORYS MAPPING SYSTEM is indicated for use in intact skin only.		
System	Computer workstation (operating system, adapter, cords, keyboard, mouse, Isolation transformer, connector cables, Isolation ethernet	Cart, Monitor, Core Processor, Keyboard, Mouse, Isolation Transformer, Cabling, Sensor Array, Second Monitor connection	Computer Workstation (monitor, main control unit, peripherals, and cords), Software/Firmware/Algorithm, Off-the-shelf (OTS) ECG (not provided) and ECG electrodes (12-Lead) (optional)
Principles of Operation and Procedure of Use	Electrocardiographic potentials are measured from the sensors on the surface of the body. A 3-dimensional model of the patient torso is obtained using the ACORYS 3D Scan Software. From these data, the system uses mathematical algorithms to determine the most appropriate cardiac geometry for the patient and uses the geometrical information to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem. If a cardiac geometry is available by means of an a priori CT scan, it can be input to the system to substitute the automatically generated cardiac geometry.	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.	12-ECG signals are received from an external compatible ECG device. Non-patient specific cardiac and torso geometries are employed, and the system leverages a pre-computed cardiac voltage library which uses forward models and mathematical algorithms to derive cardiac signals from body surface signals.
Software/ Firmware/ Algorithms	Create patient records, Segment heart and vest Electrodes, Acquire sensor array signals,	Create patient records, Segment heart and vest Electrodes, Acquire sensor array signals,	Create patient records, Estimate cardiac geometry, Estimate heart position,

CHARACTERISTIC	SUBJECT DEVICE (ACORYS MAPPING SYSTEM, K253861)	PRIMARY PREDICATE (MEDTRONIC'S CARDIOINSIGHT, K162440)	REFERENCE DEVICE (VEKTOR'S VMAP, K211546)
	Create and review maps, Estimate cardiac geometry, Estimate heart position, Automatic sensor segmentation	Create and review maps	Create and review maps
System components	<u>System:</u> ACORYS Amplifier, ACORYS Sensor Vest, ACORYS Software, ACORYS 3D Scan App, ACORYS Isolation transformer, ACORYS Connector Cables. <u>Off-the-shelf components:</u> Workstation, 3D Scan Platform.	Mapping Amplifier, Sensor Array, Software, Isolation transformer, Cabling, Workstation (w/ software) Monitor, Cart.	Software Workstation, Peripherals, ECG electrodes
Number of electrodes (sensors)	128	256	10 (12-lead ECG, not part of the system)

Sensor Vest Materials	Ag Electrodes,	Ag/AgCl Electrodes,	N/A, vMap is software

CHARACTERISTIC	SUBJECT DEVICE (ACORYS MAPPING SYSTEM, K253861)	PRIMARY PREDICATE (MEDTRONIC'S CARDIOINSIGHT, K162440)	REFERENCE DEVICE (VEKTOR'S VMAP, K211546)
	Adhesive Foam, Conductive hydrogel, Dielectric substrate, Plastic substrate.	Adhesive Foam, Conductive hydrogel, Dielectric substrate, Plastic substrate.	
Power supply	Battery <u>Characteristics (charging)</u> - 100-240 VAC - 50/60 Hz <u>Characteristics (power supply)</u> - 16.8 VDC - 6 A	Mains <u>Characteristic</u> - 100-240 VAC - 50/60 Hz	N/A, vMap is software
Use conditions	Temperature: +15ºC to +30ºC. Relative humidity: 20% to 80%.	Temperature: +15ºC to +30ºC. Relative humidity: 20% to 80%.	N/A, vMap is software
Transport conditions	Temperature: -30ºC a +60ºC. Relative humidity: 15% to 90%.	Temperature: -30ºC a +60ºC. Relative humidity: 15% to 90%.	N/A, vMap is software
Storage conditions	Temperature: +15ºC to +30ºC. Relative humidity: 15% to 90%.	Temperature: +15ºC to +30ºC. Relative humidity: 15% to 90%.	N/A, vMap is a software

5. Summary of performance and safety

Safety

The ACORYS MAPPING SYSTEM has undergone an extensive safety evaluation, conducted in compliance with the relevant standards, addressing various aspects such as biocompatibility, electrical safety, electromagnetic compatibility, and software functionality. Many of these standards are consistent with those applied to the predicate device. The table below summarizes the safety assessments conducted.

Aspect subject to evaluation	Methodology	Applicable standards
General Safety, Electrical Safety and Essential Operation	Tests conducted by a certified external laboratory (CERE, Madrid, Spain – ASCA-accredited, ASCA ID# TL-27).	EN 60601-1: 2005+ A2:2020
		IEC 60601-2-27:2014
		IEC 60601-1-6: 2010 + A2:2021
		ISO 14971:2019/ A11:2021
Electromagnetic compatibility	Tests conducted by a certified external laboratory (CERE, Madrid, Spain – ASCA-accredited, ASCA ID# TL-27).	EN 60601-1-2:2014 + A1:2020
		ISO 14971:2019/ A11:2021
Software functionality and integration tests	Software verification plan (Internal tests of functionality, integration and usability of the software components)	IEC 62304:2006 + A1:2015
		ISO 14971:2019/ A11:2021
3D Scan Accuracy	Internal verification through a calibrated test system.	-
Biocompatibility and biological safety	Cytotoxicity, sensitization and irritation testing according to applicable standards (NAMSA, Lyon, France – ASCA-accredited, ASCA ID# TL-58).	ISO 10993-1:2020
		ISO 10993-5:2009
		ISO 10993-10:2021
		ISO 10993-18:2020
		ISO 10993-23:2021
		ISO 14971:2019/ A11:2021

Performance Testing – Bench

Mathematical modeling was implemented to assess the effect of each existing technological differences with respect to the predicate device in the performance of our system. No adverse impact on mapping accuracy was observed due to the differences; indeed, the ACORYS configuration yielded equivalent or improved localization accuracy in mathematical simulation.

Performance Testing - Clinical

Clinical evaluation was conducted to demonstrate that the performance and safety of the subject device, the ACORYS MAPPING SYSTEM, is substantially equivalent to that of the proposed predicate device, the Medtronic's CardioInsight system (K162440). The system was evaluated in a multicenter clinical investigation conducted in three hospitals in Spain, including 199 patients with different arrythmia types. The primary objective of the study was to evaluate the accuracy of the positive predictive value of the new ECGI system in identifying the relevant arrhythmic region and/or the correct placement of a pacemaker/defibrillator device.

Results demonstrated performance comparable to the predicate device, and no device-related adverse events were reported during the use of the ACORYS MAPPING SYSTEM, supporting substantial equivalence.

6. Conclusion

In conclusion, the ACORYS MAPPING SYSTEM meets all the necessary performance and safety criteria to be considered substantially equivalent to the predicate and reference devices. It offers a safe, non-ionizing alternative with similar performance for arrhythmia mapping, confirming its readiness for use in clinical practice.