August 16, 2021

CardioNXT, Inc.
Jerome Edwards
President
12011 Tejon Street, Suite 700
Westminster, Colorado 80234

Re: K201094
Trade/Device Name: iMap™ 3D Mapping & Navigation System (iMap™ System)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DRF
Dated: August 13, 2021
Received: August 16, 2021

Dear Jerome Edwards:

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,

Aneesh Deoras
Assistant Director (Acting)
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)*
K201094

Device Name

iMap™ 3D Mapping & Navigation System (iMap™ System)

Indications for Use *(Describe)*

The CardioNXT iMap™ 3D Mapping & Navigation System is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures.

The MultiLink CS Catheter is used for electrogram recording and as a navigation reference during conventional electrophysiological procedures.

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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510(k) Summary

iMap™ 3D Mapping & Navigation System

K201094

1. Submission Sponsor

CardioNXT, Inc.
12011 Tejon Street, Suite 700
Westminster, Colorado 80234
USA
Contact: Jerome Edwards
Title: Chief Executive Officer
Phone: 615.473.9012
Email: jerome.edwards@cardionxt.com

2. Date Prepared

August 13, 2021

3. Device Identification

Trade/Proprietary Name:	iMap™ 3D Mapping & Navigation System (iMap™ System)
Common/Usual Name:	Programmable diagnostic computer
Classification Name:	Computer, Diagnostic, Programmable
Regulation Number:	21 CFR §870.1425
Product Code:	DQK; Computer, Diagnostic, Programmable
Device Class:	Class II
Classification Panel:	Cardiovascular

4. Predicate Device Information

Predicate Device	Primary or Secondary Predicate	Manufacturer	510(k) No.
EnSite Precision™ Cardiac Mapping System	Primary	Abbot St. Jude	K160210
EnSite™ Velocity Cardiac Mapping System with EnSite™ Velocity Surface Electrode Kit (Commonly known as the NavX System)	Secondary	Abbot St. Jude	K160186
IBI Inquiry Diagnostic Catheter (Secondary Predicate)	Secondary	Abbot St. Jude	K961924

5. Indication for Use Statement

The CardioNXT iMap™ 3D Mapping & Navigation System is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. The MultiLink CS Catheter is used for electrogram recording and as a navigation reference during conventional electrophysiological procedures.

6. Device Description

The CardioNXT iMap™ 3D Mapping and Navigation System (iMap™ System) is a catheter navigation and mapping system, capable of displaying the three-dimensional (3D) position of conventional electrophysiology catheters, as well as displaying cardiac electrical activity as waveform traces and as electroanatomical maps of the cardiac chamber. The contoured surfaces of these three-dimensional maps are based on the anatomy of the patient's cardiac chamber. The iMap™ System utilizes electromagnetic tracking and impedance tracking to track conventional catheters and paint the surfaces of cardiac chambers in 3D to generate a patient-specific image of the heart, also called a geometry. The iMap System measures cardiac electrogram (EGM) information from navigated catheter electrodes throughout the heart and displays this information on the patient-specific geometry. The iMap System utilizes a Coronary Sinus(CS)catheter with both electromagnetic sensors and electrodes as a reference for its navigation coordinate system.

7. Substantial Equivalence Discussion

The following tables compares the iMap™ 3D Mapping & Navigation System and Multilink CS Catheter to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Manufacturer	**Subject Device: CardioNXT, Inc.**	**Primary Predicate: Abbott / St. Jude**	**Secondary Predicate: Abbott / St. Jude**	**Device Comparison**
Trade Name	**iMap™ 3D Mapping and Navigation System**	**EnSite™ Precision Cardiac Mapping System V2.0.1**	**EnSite™ Velocity Cardiac Mapping System v4.0.2 with EnSite™ Velocity Surface Electrode Kit**	
510(k) Number	K201094	K160210	K160186 (with patches)	Not applicable
Product Code	DQK	DQK	DQK	Same
Regulation Number	21 CFR 870.1425	21 CFR 870.1425	21 CFR 870.1425	Same
Regulation Name	Programmable Diagnostic Computer	Programmable Diagnostic Computer	Programmable Diagnostic Computer	Same
Indications for Use	The CardioNXT iMap 3D Mapping & Navigation	The EnSite™ Precision Cardiac Mapping	The EnSite™ Velocity™ Cardiac Mapping System	Similar with minor variation.

Manufacturer	**Subject Device: CardioNXT, Inc.**	**Primary Predicate: Abbott / St. Jude**	**Secondary Predicate: Abbott / St. Jude**	**Device Comparison**
Trade Name	**iMap™ 3D Mapping and Navigation System**	**EnSite™ Precision Cardiac Mapping System V2.0.1**	**EnSite™ Velocity Cardiac Mapping System v4.0.2 with EnSite™ Velocity Surface Electrode Kit**	
	System is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. The MultiLink CS Catheter is used for electrogram recording and as a navigation reference during conventional electrophysiological procedures.	System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ Precision System interfaces to either the MediGuide™ Technology system or the EnSite™ Precision Module to combine and display magnetic processed patient positioning and navigation mapping information. When used with the EnSite™ Array™ Catheter, the EnSite™ Precision™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. **OR** When used with an EnSite™ Precision™ Surface Electrode Kit, the EnSite™ Precision™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.	is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. When used with the EnSite™ Array™ Catheter, the EnSite™ Velocity™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. **OR** When used with an EnSite™ Velocity™ Surface Electrode Kit, the EnSite™ Velocity™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.	While the exact wording of the indications for use is not identical, all elements of the indications for the CardioNXT iMap System are contained within the indications for use for the predicate devices.
Physical Characteristics				
System Components to	iMap Controller iMap Field Generator (NDI)	Ensite Precision™ Link (NDI)	Ensite™ Amplifier NavLink GenConnect	Similar components

Manufacturer	**Subject Device: CardioNXT, Inc.**	**Primary Predicate: Abbott / St. Jude**	**Secondary Predicate: Abbott / St. Jude**	**Device Comparison**
Trade Name	**iMap™ 3D Mapping and Navigation System**	**EnSite™ Precision Cardiac Mapping System V2.0.1**	**EnSite™ Velocity Cardiac Mapping System v4.0.2 with EnSite™ Velocity Surface Electrode Kit**	
Achieve Intended Use	iMap Patient Interface iMap Ablation Adapter iMap RF Ground Filter iMap Power Unit iMap Computer workstation Monitor, keyboard, and mouse	Ensite™ Field Frame (NDI) Ensite™ Amplifier NavLink GenConnect Computer workstation Monitor, keyboard, and mouse	Computer workstation Monitor, keyboard, and mouse	
Patient Patches	6 external patches plus electromagnetic references.	6 external patches with one reference patch, plus electromagnetic references.	6 external patches with one reference patch	Similar
Catheters	Compatible EP catheters and Multilink CS Catheter	Compatible EP catheters and at least one magnetic sensor-based catheter; Advisor FL Circular Mapping Catheter	Compatible EP catheters	Similar
Technology				
Principle of Operation	Measure the impedance position and electromagnetic position of catheters and display position of both on a computer screen. Measure EGMs and display that information as tracings and as 3D model information based on a patient's cardiac chamber.	Measure the impedance position and electromagnetic position of catheters and display position of both on a computer screen. Measure EGMs and display that information as tracings and as 3D model information based on a patient's cardiac chamber.	Measure the impedance position of catheters and display position on a computer screen. Measure EGMs and display that information as tracings and as 3D model information based on patient's cardiac chamber.	Technological and performance characteristics are similar.
Localization Technology	Proprietary Patch to Electrode Impedance measurement Northern Digital (NDI) – Aurora electromagnetic Window Field Generator	Proprietary Patch to Electrode Impedance measurement Northern Digital (NDI) – Aurora electromagnetic Window Field Generator	Proprietary Patch to Electrode Impedance measurement	Similar Impedance Localization. Same Electromagnetic localization.
3D Geometry of Endocardial Surface	Chamber surface (Geometry) gathered by navigated catheter.	Chamber surface (Geometry) gathered by navigated catheter.	Chamber surface (Geometry) gathered by navigated catheter.	Same.

Manufacturer	**Subject Device: CardioNXT, Inc.**	**Primary Predicate: Abbott / St. Jude**	**Secondary Predicate: Abbott / St. Jude**	**Device Comparison**
Trade Name	**iMap™ 3D Mapping and Navigation System**	**EnSite™ Precision Cardiac Mapping System V2.0.1**	**EnSite™ Velocity Cardiac Mapping System v4.0.2 with EnSite™ Velocity Surface Electrode Kit**	
Contact Electro-anatomical Mapping	Activation and Voltage.	Activation and Voltage.	Activation and Voltage.	Same.
Simultaneous Navigation of multiple catheters	Multiple catheters, with at least Multilink CS Catheter	Multiple catheters, with at least one magnetic sensor-based catheter.	Multiple catheters.	Similar.

Manufacturer	**Subject Device: CardioNXT, Inc.**	**Primary Predicate: Abbott / St. Jude / Irvine Biomedical Inc.**	**Device Comparison**
Trade Name	**MultiLink CS Catheter**	**IBI Inquiry Diagnostic Electrophysiology Catheter**	
510(k) Number	K201094	K961924	Not applicable
Product Code	DRF	DRF	Same
Regulation Number	21 CFR 870.1220	21 CFR 870.1220	Same
Indications for Use	The CardioNXT iMap 3D Mapping & Navigation System is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. The MultiLink CS Catheter is used for electrogram recording and as a navigation reference during conventional electrophysiological procedures.	The Inquiry™ fixed curve and steerable electrophysiology catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.	Similar. While the exact wording of the indications for use is not identical, all elements of the indications for the MultiLink CS Catheter are contained within the indications for use for the predicate device.
Device Description	Steerable 6 Fr. decapolar (plus two additional proximal electrodes and electromagnetic sensors) electrophysiology recording catheter.	Steerable 6 Fr. decapolar electrophysiology recording catheter.	Similar
Physical Characteristics			
Shaft and Electrodes	110cm shaft, 6Fr, 10 electrodes with 2-5-2 spacing and 2 electrodes along proximal curve.	110cm shaft, 6Fr, 10 electrodes with 2-5-2 spacing.	Same, Multilink has 2 additional electrodes

Manufacturer	Subject Device: CardioNXT, Inc.	Primary Predicate: Abbott / St. Jude / Irvine Biomedical Inc.	Device Comparison
Trade Name	**MultiLink CS Catheter**	**IBI Inquiry Diagnostic Electrophysiology Catheter**	
Handle	Push/Pull knob, uni-directional deflection with connector	Push/Pull knob, uni-directional deflection with connector	Similar

8. Performance Data

As part of demonstrating safety, effectiveness, and substantial equivalence of the iMap™ 3D Mapping & Navigation System, CardioNXT, Inc. completed bench and animal testing. The iMap™ 3D Mapping & Navigation System meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device as evidenced by the following testing:

- CardioNXT iMap System verification testing
- GLP animal study
- Bench Testing demonstrating substantially equivalent safety, performance, and accuracy to predicate
- Electrical Safety Testing (ANSI/AAMI ES60601-1:2005/A1:2012)
- Electrical Safety Testing (IEC 60601-2-2:2017)
- Electromagnetic Compatibility Testing (IEC 60601-1-2:2014, EN 55011:2009)
- Biocompatibility Testing (ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2017)
- Cleaning and Sterilization Testing per Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Healthcare Settings: Validation Methods and Labeling
- Storage and Transport Testing (ISTA 2A)
- Diagnostic Intravascular Catheter Testing (ISO 10555-1:2013)
- Software verification and validation testing per IEC 62304/FDA Guidance
- Compatibility testing in a cardiac electrophysiology lab environment
- Usability testing demonstrating usability by licensed cardiac electrophysiologist physicians

9. Conclusions

Bench testing demonstrates the iMap™ 3D Mapping & Navigation System meets performance specifications. Validation testing through a GLP controlled animal study further demonstrated performance of the iMap™ 3D Mapping & Navigation System and substantial equivalence to the predicate. As such, this collection of testing demonstrates the substantial equivalence of the iMap System to the predicate device.