October 24, 2018

Philips Medical Systems Nederland B.V.
Gina Crossetta
VP, Regulatory and Quality
Veenpluis 4, -6
PC Best, 5684 Nl

Re: K180940
Trade/Device Name: KODEX EPD™ System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 26, 2018
Received: September 26, 2018

Dear Gina Crossetta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180940

Device Name
KODEX – EPD™ System

Indications for Use *(Describe)*
The KODEX-EPD™ System is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD™ System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Applicant: Philips Medical Systems Nederland B.V.
Veenpluis 4, - 6, 5684 PC Best, Netherlands

Contact Person: Gina Crossetta
Vice President, Regulatory and Quality

Phone: (845) 558-2772
Email: ginac@epd-medical.com

Date Prepared: October 18, 2018

Device Trade Name: KODEX – EPD™ System

Device Common Name: Cardiac Mapping and Navigation Device

Classification Name: Programmable Diagnostic Computer

Regulation Number: Class II, 21 CFR 870.1425

Product Code: DQK

Predicate Device: CARTO 3 EP Navigation System (K133916)

Device Description:

The KODEX-EPD™ system is a catheter-based cardiac mapping system designed to acquire and analyze individual data points, and use this information to display 3D electro-anatomical maps of the human heart in real-time. The information needed to create the cardiac maps is acquired using standard EP catheters and proprietary external patches.

KODEX-EPD™ continuously collects electromagnetic signals from all patches and electrodes attached to it. The system then uses these to create a 3D image of the chamber, and superimposes the real time catheter position on the chamber image. In addition, the KODEX-EPD™ system supports representation of the electrical activity of cardiac chambers, based on the intra cardiac signals received from the all catheters and body surface signals.

The KODEX-EPD™ system includes the KODEX Processing Unit, BS Pin Box, Diagnostic Catheter Connection Box, Recording System Connection Box, Workstation, Foot Pedal and KODEX-EPD™ External Patches.

Intended Use/Indications for Use:
The KODEX-EPD™ System is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD™ System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure.

Summary of Technology Characteristics:
Table 1 provides a comparison of the technological characteristics for the KODEX – EPD™ System and the predicate device.

Table 1: Comparison of Technological Characteristics for the KODEX – EPD™ System and Predicate

	KODEX – EPD™ Mapping System	Biosense Webster's CARTO 3 EP Navigation System[1]	Comments
Regulatory			
510(k)	TBD	K133916	N/A
Device class	II	II	Same
Classification	Programmable diagnostic-computer Class II; 21 CFR, 870.1425	Programmable diagnostic-computer Class II; 21 CFR, 870.1425	Same
Product code	DQK	DQK	Same
Indications/Intended use	The KODEX-EPD™ System is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD™ System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure.	The intended use of the CARTO 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure. The system has no special contraindications.	Same
Intended users	EP's and EP lab staff trained on the use of the system	EP's and EP lab staff trained on the use of the system	Same
Physical Characteristics			

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf13/K133916.pdf

	KODEX – EPD™ Mapping System	Biosense Webster's CARTO 3 EP Navigation System[1]	Comments
System Components	The KODEX – EPD™ system is comprised of the following components: 1) KODEX-EPD PU: Processing Unit 2) KODEX-EPD -WS: Workstation with Graphic User Interface 3) KODEX-EPD BS Pin Box: a. Seven input pins for body patches. b. One input pin for ground patch (right leg). 4) D700 Diagnostic catheters connection boxes: boxes with 16 optional input pin connectors. 5) KODEX-EPD RS connection Boxes: boxes with 20 optional output pin connectors. 6) Foot pedals 7) Keyboard and mouse 8) Cart (optional)	The CARTO 3 system is comprised of the following components: 1) Patient Interface Unit (PIU) 2) Workstation with Graphic User Interface 3) Patches Connection Box and Cables 4) Intracardiac In Port 5) Intracardiac Out Port 6) Foot pedals 7) Keyboard, and mouse 8) Cart (optional) 9) Power Supply 10) Monitor 11) Location Pad	Similar components
Patient Patches/ electrodes	6 external patches plus one right leg patch	6 external reference patches	KODEX relies on dielectric measurements from the external patches for mapping and navigation. Since each patch can have a different potential offset the measurements are referenced against an additional patch; the right leg patch. For the reasons stated below, the reliance on dielectric mapping does not raise any new questions of safety or effectiveness.

	KODEX – EPD™ Mapping System	Biosense Webster's CARTO 3 EP Navigation System[1]	Comments
			The KODEX System includes the external patches while the CARTO 3 patches are cleared separately (K061468). This doesn't raise any new questions of safety or effectiveness. The CARTO 3 patches are cleared separately so that they may be used for multiple devices.
Catheters	Compatible EP catheters	Specialized catheters with integrated magnetic sensor; several compatible diagnostic and therapeutic catheters	Same
Foot Pedals	Commercial foot pedals used for hands free acquisition of points (Local Activation Time and tagging points)	Foot pedals used for hands free acquisition of points	Same
Technology			
Principles of operation	Mapping of electrical fields and impedances (dielectric mapping)	Triangulation of magnetic fields (magnetic technology) and impedance	Both systems achieve the desired features (navigation, accuracy, electroanatomical mapping, etc) by mapping impedance with either electrical fields (KODEX) or magnetic fields (CARTO 3).
Location Technology	Impedance localization technology (Dielectric); any catheter	Magnetic sensor technology for location and orientation of a specialized catheter with magnet sensor on tip and impedance localization	Both systems achieve the desired features (navigation, accuracy, electroanatomical mapping, etc) by mapping impedance with either electrical fields (KODEX) or magnetic fields (CARTO 3).
3D Geometry mapping by aggregating catheter location; Geometry	Yes, based on ablation catheter and Dielectric technology	Yes, based on diagnostic and ablation catheters	Same

	KODEX – EPD™ Mapping System	Biosense Webster's CARTO 3 EP Navigation System[1]	Comments
rotation and flexible display			
Flattened 3D view of the whole cardiac chamber	Yes, PANOv flattened chamber display	No	The flattened chamber display is an added feature provided by KODEX but doesn't raise new questions of safety or effectiveness. It is simply an additional, optional viewing option that provides an alternative depiction of the chamber, but the standard view provided by both systems (i.e., without flattening) remains the same, as shown in the performance testing.
Simultaneous Navigation of multiple catheters	Yes, 1 compatible ablation catheter and up to 3 diagnostic catheters	Yes, 1 sensor enabled ablation catheter and several diagnostic catheters.	Same
Electrograms for activation and voltage mapping.	Yes. Local Activation Time maps, voltage maps and propagation maps	Yes, Local Activation Time maps, impedance maps and propagation maps	Both systems provide electroanatomical maps. The maps provided by the KODEX System are a subset of those provided by CARTO, and they are the most widely used.
Ablation parameter visualization and tagging tool	Yes. KODEX provides catheter stability, intracardiac electrical activation information, and during ablation, impedance drop and temperature as read from the RF generator. Ablation point tagging is conducted based on a user defined combination of parameters and thresholds. In addition the KODEX system provides power, power integral over ablation time and duration.	Yes, optional (Visitag Module). CARTO 3 provides catheter stability, contact force, intracardiac electrical activation information, and during ablation, impedance drop and temperature as read from the RF generator. Ablation point tagging is conducted based on a user defined combination of parameters and thresholds.	Both systems display RF generator communicated parameters. Both systems provide catheter stability, intracardiac electrical activation information, and during ablation, impedance drop and temperature as read from the RF generator. Ablation point tagging is conducted based on a user

	KODEX – EPD™ Mapping System	Biosense Webster's CARTO 3 EP Navigation System[1]	Comments
			defined combination of parameters and thresholds. While the KODEX System provides some additional parameters not provided by CARTO (power, power integral over ablation time, and duration), and CARTO 3 provides one additional parameter (contact force), these provide the physician with additional information but do not raise new questions of safety or effectiveness. Based on performance testing conducted these additional features perform as intended.
Compatibility with RF generator	Yes, Stockert 70 and Maestro 4000	Yes	Both systems are compatible with RF generators

Substantial Equivalence Discussion:
The indications for use for the predicate device is identical to the proposed indications for use for the KODEX – EPD™ System. As demonstrated in Table 1 above, any differences in the technological characteristics do not raise any questions of safety or effectiveness. Thus the KODEX – EPD™ System is substantially equivalent to the predicate device.

Performance Data
The company conducted extensive bench and animal testing which demonstrated that the KODEX – EPD™ System meets its design specifications and is substantially equivalent to the predicate device. Specifically, the following bench and animal testing was conducted:

- KODEX – EPD™ System verification testing
- Compatibility testing
- Software verification and validation (ISO 62304:2006 + A1:2015)
- Transportation testing
- Electromagnetic Compatibility (IEC 60601-1-2, IEC 60601-2-27)
- Electrical Safety Testing (IEC 60601-1, IEC 62366:2007 + A1:2014, IEC 62304:2006 + A1:2014)
- GLP animal study
- Usability testing
- Biocompatibility testing (ISO 10993-1:2009, ISO 10993-5:2009 and ISO 10993-10:2010)

The testing demonstrated that the product meets is performance specifications and performs as intended. In addition, the KODEX – EPD™ System was found to be substantially equivalent to the predicate device.

Conclusions
Extensive bench testing was conducted which demonstrated that the KODEX – EPD™ System meets its performance specifications. The company also conducted validation testing in the form of animal and usability to evaluate the overall performance of the KODEX – EPD™ System. This collection of testing demonstrates the safety and effectiveness of the KODEX – EPD™ System its substantial equivalence to the predicate device.