FDA **U.S. FOOD & DRUG**
ADMINISTRATION

October 24, 2022

Philips Medical Systems Nederland, B.V. (PMSN)
Betina Schepers
Head of Quality, EPD Solutions
Veenpluis 6, 5684 PC
Best, Netherlands

Re: K212493
    Trade/Device Name: KODEX-EPD™ System 1.5.0
    Regulation Number: 21 CFR 870.1425
    Regulation Name: Programmable Diagnostic Computer
    Regulatory Class: Class II
    Product Code: DQK
    Dated: September 21, 2022
    Received: September 21, 2022

Dear Betina Schepers:

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
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

510(k) Number *(if known)*
K212493

Device Name
KODEX-EPD™ System 1.5.0

Indications for Use *(Describe)*

The KODEX-EPD™ System 1.5.0 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD ™ System 1.5.0 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.

510(k) SUMMARY
KODEX-EPD™ System 1.5.0

Submitter: Philips Medical Systems Nederland B.V. (d/b/a EPD Solutions)
                                         Veenpluis 6, 5684 PC Best, Netherlands

Contact Person: Betina Schepers
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Date Prepared: October 21, 2022

Name of Device: KODEX – EPD™ System 1.5.0
Common or Usual Name: Cardiac Mapping and Navigation Device
Classification Name: Programmable Diagnostic Computer
Regulatory Class: Class II, 21 CFR 870.1425
Product Code: DQK
Predicate Device: KODEX – EPD™ System (K180940)

Device Description
The KODEX-EPD™ System 1.5.0 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 electrophysiological (EP) catheters and proprietary external sensors.

KODEX – EPD™ continuously collects electromagnetic signals from all sensors 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 1.5.0 supports representation of the electrical activity of cardiac chambers, based on the intra cardiac signals received from the all catheters and body surface signals.

Intended Use / Indications for Use
The KODEX-EPD™ System 1.5.0 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD™ System 1.5.0 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 Technological Characteristics
Table 1 provides a comparison of the technological characteristics for the KODEX – EPD™ System 1.5.0 and the predicate device.

Table 1: Comparison of Technological Characteristics for the KODEX – EPD™ System 1.5.0 and Predicate Device

	Subject Device KODEX – EPD™ System 1.5.0	Predicate Device KODEX – EPD™ System	Comments
Regulatory			
510(k)	K212493	K180940	N/A
Device class	Class II	Class II	Same
Classification	Programmable diagnostic computer; 21 CFR 870.1425	Programmable diagnostic computer; 21 CFR 870.1425	Same
Product code	DQK	DQK	Same
Indications/Intended use	The KODEX-EPD™ System 1.5.0 is indicated for catheter-based cardiac electrophysiological (EP) procedures. The KODEX-EPD™ System 1.5.0 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 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.	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			

	Subject Device KODEX – EPD™ System 1.5.0	**Predicate Device KODEX – EPD™ System**	**Comments**

System Components	The KODEX – EPD™ System 1.5.0 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) Diagnostic catheters connection boxes (formerly referred to as D700 Diagnostic catheter 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)
	9) Gemalto key
	10) Catheter key
		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. Six inputs for body sensors.
		  b. One input pin for reference sensor (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)
			Identical components except that the subject device includes use of a Gemalto key and catheter key. The Gemalto key encrypts the software. The catheter key is a stand-alone connector specific to the type of catheter to be used by the customer. The keys serve commercial purposes and have no impact on the clinical functionality or performance of the system.

Patient Patches/ electrodes	Six (6) external sensors (formerly referred to as patches) plus one (1) right leg patch.	Six (6) external sensors plus one (1) right leg sensor.	Same
Catheters	Compatible with off the shelf EP catheters.	Compatible with off the shelf EP catheters.	Same
Foot Pedals	Commercial foot pedals used for hands free acquisition of points (Local Activation Time and tagging points).	Commercial foot pedals used for hands free acquisition of points (Local Activation Time and tagging points).	Same
Technology			
Principles of operation	Mapping of electrical fields and impedances (dielectric mapping): Mapping of global induced electrical fields and impedances (dielectric	Mapping of electrical fields and impedances (dielectric mapping).	Same. The actual principles of operation are identical, however, the language for the subject device has been

	Subject Device KODEX – EPD™ System 1.5.0	Predicate Device KODEX – EPD™ System	Comments
	mapping) for intra-body localization. Local interrogation of locally induced electrical fields and impedances (dielectric mapping) for electrode-tissue interface characterization.		revised in order to provide additional explanation about how the technology is used.
Location Technology	Impedance localization technology (Dielectric); any catheter. Impedance intra-body localization technology (Dielectric); for tracking and navigating any catheter inside the globally induced electrical field.	Impedance localization technology (Dielectric); any catheter.	Same. The actual principles of operation are identical, however, the language for the subject device has been revised in order to provide additional explanation about how the technology is used.
3D Geometry mapping by aggregating catheter location; Geometry rotation and flexible display	Yes, based on ablation and/or diagnostic catheters, and Dielectric technology.	Yes, based on ablation catheter and Dielectric technology.	Same principle, the KODEX-EPD 1.5.0 utilizes both ablation and diagnostic catheters that are pre-qualified.
Flattened 3D view of the whole cardiac chamber	Yes, PANO flattened chamber display.	Yes, PANO flattened chamber display.	Same
Simultaneous Navigation of multiple catheters	Yes, one (1) off-the-shelf ablation catheter and up to four (4) diagnostic catheters.	Yes, one (1) off the shelf ablation catheter and up to three (3) diagnostic catheters.	The KODEX-EPD 1.5.0 has been qualified for use with up to four (4) diagnostic catheters as opposed to three (3) for the predicate device. The use of up to four (4) catheters has been verified and does not raise any new questions of safety or effectiveness.
Electrograms for activation and voltage mapping.	Yes. Local Activation Time maps, voltage maps and propagation maps.	Yes. Local Activation Time maps, voltage maps and propagation maps.	Same

	Subject Device KODEX – EPD™ System 1.5.0	Predicate Device KODEX – EPD™ System	Comments
Ablation parameter visualization and tagging tool	Yes. KODEX-EPD System 1.5.0 provides catheter stability, intracardiac electrical activation information, and during ablation, impedance drop and temperature as read from the radiofrequency (RF) generator. Ablation point tagging is conducted based on a user defined combination of parameters and thresholds. In addition, the KODEX-EPD System 1.5.0 provides power, power integral over ablation time and duration.	Yes. KODEX-EPD System provides catheter stability, intracardiac electrical activation information, and during ablation, impedance drop and temperature as read from the radiofrequency (RF) generator. Ablation point tagging is conducted based on a user defined combination of parameters and thresholds. In addition, the KODEX-EPD System provides power, power integral over ablation time and duration.	Same
Compatibility with RF generator	Yes, Stockert 70, Maestro 4000, and SmartAblate.	Yes, Stockert 70 and Maestro 4000.	Both systems are compatible with RF generators.
Tissue Engagement Viewer	Tissue Engagement Viewer (TEV) is a software feature which provides information regarding the engagement level of an ablation catheter with the tissue by tracking catheter's proximity to the tissue together with the real-time change in local dielectrics. TEV is not available for diagnostic catheters. The tissue engagement viewer displays visual feedback on the tissue engagement of three (3) states: No Touch (NT), Touch (T), High Touch (HT). TEV is active, following manual zeroing in the blood pool when not in contact with the myocardial wall, only when the RF ablation is not in use.		The TEV feature enables verification that the catheter is in close proximity and in the desired engagement level with the cardiac wall, facilitating generation of improved and more accurate anatomical reconstruction as well as electro-anatomical maps. Refraining from acquiring points in higher than desired engagement level can prevent tissue displacement or tenting and negatively impacting quality and correctness of both reconstruction and electro-anatomical maps. The feature is based on the same characteristics that exist in the predicate device; local interrogation of locally induced

	Subject Device KODEX – EPD™ System 1.5.0	Predicate Device KODEX – EPD™ System	Comments
			electrical fields and impedances (dielectric mapping) for electrode-tissue interface characterization. The feature is intended to supplement common clinical practice for real time verification of catheter location (e.g., inspection of IC signals and annotations, fluoroscopy or other imaging modality, etc.). While the TEV feature utilizes dielectric mapping to additional visual feedback to the user this additional information does not raise any new questions of safety or effectiveness.

	Subject Device KODEX – EPD™ System 1.5.0	Predicate Device KODEX – EPD™ System	Comments
Cryo Occlusion Viewer	Pulmonary Vein (PV) occlusion state derived from local change in dielectrics read off the spiral mapping catheter's electrodes, placed inside the PV, when the cryoballoon is inflated at the PV ostium and/or when dye is being injected. PV occlusion assessment is intended to be used as additional method to confirm occlusion, next to contrast injection and other appropriate visualization techniques as described in the cryoballoon technical manual. The feature facilitates cryoballoon Pulmonary Vein Isolation procedures without modifying or replacing the recommended workflow and by providing an additional method to confirm pulmonary vein occlusion.		The KODEX-EPD™ System 1.5.0 tracks and localizes the Achieve Spiral Mapping Catheter, and generates a detailed 3D and panoramic image and an electro-anatomical map of the left atrium and adjacent pulmonary veins, using (1) the same first induced intra-body global electrical field generated by the body surface sensors, (2) the same raw signals, and (3) the same intra-body tracking, navigation, imaging, and electro-anatomical mapping technology as the predicate device. The subject device uses the same characteristic dielectric change in field shape and tissue signature and the same technology (i.e., continuously interrogating locally the change in electrical fields) as the predicate device to provide additional insight about PV occlusion state and cryoballoon appositioning. This feature does not raise any new questions off safety or effectiveness.

Substantial Equivalence Discussion:

The KODEX-EPD™ System 1.5.0 has the same intended use as the legally marketed predicate and reference devices. The indications for use for the KODEX – EPD™ System 1.5.0 is identical to the proposed indications for use for the predicate device and nearly identical to the indications for use for the reference device. 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 1.5.0 is substantially equivalent to the predicate and reference devices.

Performance Data

The company conducted extensive bench and animal testing which demonstrated that the KODEX – EPD™ System 1.5.0 meets its design specifications and is substantially equivalent to the predicate and reference devices. Specifically, the following bench and animal testing was conducted:

- KODEX – EPD™ System 1.5.0 verification testing
- Software verification and validation (IEC 62304)
- Electromagnetic Compatibility (IEC 60601-1-2, IEC 60601-2-27)
- Electrical Safety Testing (ANSI/AAMI ES 60601-1, IEC 62366, IEC 62304)
- GLP animal study
- Usability testing
- The Cryo Occlusion Viewer was verified through system software verification that demonstrated that the software requirements specifications were met, regression testing that demonstrated that the system functionality was not impacted by upgrade to version 1.5.0., verification of the Cryo Occlusion Viewer and verification of the compatibility and interoperability of the Medtronic Achieve Catheter when connected to the KODEX-EPD™ System. In addition, the Cryo Occlusion Viewer was validated through retrospective analysis of KODEX-EPD™ cases for which KODEX occlusion status was compared to venography, an acute animal study and as part of a summative usability study. Verification and validation testing demonstrated that the Cryo Occlusion viewer met its specifications and performed as intended.
- The Tissue Engagement Viewer (TEV) was assessed on the bench to verify the capability to indicate if the catheter tip touches the tissue or not, indicate the touch level in latency up to 1 second and to indicate if the catheter tip touches the tissue with high force. The feature was validated in an acute GLP animal study in which the clinician first established contact guided by clinical standards (fluoroscopy, EGM, impedance, ICE) and then verified TEV utilizing KODEX-EPD™ SW 1.5.0. At each location the engagement was increased from no touch, to touch to high touch based on these standards and then compared TEV on KODEX-EPD™ SW v.1.5.0. Verification and validation testing demonstrated that the TEV feature met its specifications and performed as intended.

The testing demonstrated that the product meets its performance specifications and performs as intended. In addition, the KODEX – EPD™ System 1.5.0 was found to be substantially equivalent to the predicate and reference devices.

Conclusions

After analyzing the intended use/indications for use, technological characteristics (including fundamental operating principle, functional characteristics, design features and performance characteristics) and labeling, the Company has concluded that the subject device, the KODEX-EPD™ System 1.5.0, is substantially equivalent to the predicate device. The only technological differences between the KODEX – EPD™ System 1.5.0 and its predicate device are the Cryo Occlusion Viewer and Tissue Engagement Viewer. These technological differences do not present different questions of safety or effectiveness as compared to the legally marketed predicate device because the features are only intended to provide the physician with additional information which supplements common clinical practice. Thus, the KODEX – EPD™ System 1.5.0 is substantially equivalent to the KODEX – EPD™ System, cleared in October 2018 (K180940).