Philips India Limited
% Nidhi Bathwal
Regulatory Operations Specialist
Plot No. B-79, MIDC, Phase II, Chakan,
Taluka-Khed, Village - Savardari
Pune, Maharashtra 410501
INDIA

November 16, 2017

Re: K173187
Trade/Device Name: MobileDiagnost M50
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: October 18, 2017
Received: October 19, 2017

Dear Nidhi Bathwal:

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. 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.

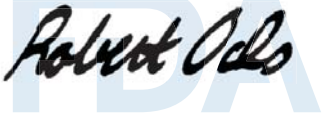
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173187

Device Name

MobileDiagnost M50

Indications for Use *(Describe)*

The MobileDiagnost M50 is a mobile radiographic system used for general X-ray imaging. This system can be used for taking x-ray images of patients who can't be moved to a fixed system. Applications include examinations of chest, upper and lower extremities, spinal column, skull radiography and abdominal cavities.
MobileDiagnost M50 is not suitable for Mammography.

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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7. 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	September 29, 2017	
Manufacturer:	Philips India Limited Plot No. B-79, MIDC, Phase-II, Chakan Taluka - khed, Village - Savardari District: Pune Maharashtra 410501 India Establishment Registration Number: 3010685285	
Primary Contact Person:	Nidhi Bathwal Title: Regulatory Operations Specialist Phone: 91-206635 7814 E-mail: nidhi.bathwal@philips.com	
Secondary Contact Person	Karthik Hoskere Title: Regulatory Operations Specialist Phone: 91-206635 7814 E-mail: karthik.hoskere@philips.com	
Device Name:	*MobileDiagnost M50*	
Classification:	Classification Name:	Mobile X-ray system
	Classification Regulation:	21CFR 892.1720
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Primary Product Code:	IZL
	Secondary Product Code:	MQB

Primary Predicate Device:	Trade Name:	MobileDiagnost wDR 2.0
	Manufacturer:	SEDECAL SA
	510(k) Clearance:	K141895 (September 18, 2014)
	Classification Regulation:	21 CFR, Part 892.1720
	Classification Name:	Mobile X-Ray System
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Primary Product Code:	IZL
	Secondary Product Code:	MQB
Reference Device:	Trade Name:	Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4)
	Manufacturer:	Varian Medical Systems
	510(k) Clearance:	K161459 (September 6, 2016)
	Classification Regulation:	21 CFR 892.1680
	Classification Name:	Stationary X-ray system
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	MQB
Reference Device:	Trade Name:	Eleva Workspot with SkyFlow
	Manufacturer:	Philips Medical Systems
	510(k) Clearance:	K153318 (December 22, 2015)
	Classification Regulation:	21 CFR 892.1680
	Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	MQB
	Secondary Product Code:	LLZ

Device Description: The *MobileDiagnost M50* is a digital mobile X-ray system, used to perform X-ray examinations in different locations of a hospital,

particularly for the patient who cannot be transferred to a fixed X-ray room. The *MobileDiagnost M50* allows the user to take X-rays on a digital wireless detector and the image can then be viewed on the Eleva Workspot.

The *MobileDiagnost M50* consists of a mobile base unit and a user interface combined with a flat solid state X-ray detector. It is used by the operator to generate, process and handle digital X-ray images.

Indications for Use:

The MobileDiagnost M50 is a mobile radiographic system used for general X-ray imaging. This system can be used for taking x-ray images of patients who can't be moved to a fixed system. Applications include examinations of chest, upper and lower extremities, spinal column, skull radiography and abdominal cavities. MobileDiagnost M50 is not suitable for Mammography.

Fundamental Scientific Technology:

The *MobileDiagnost M50* employs the same basic construction and fundamental scientific technology as the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895), with regards to the functionality of the following components: high-voltage generator, dual-focus rotation anode X-Ray tube, manual beam limiting device, digital wireless detector, and workstation for post-processing, storage and viewing images (see the comparison table comparing the *MobileDiagnost M50* to the currently marketed and predicate MobileDiagnost wDR 2.0 provided below).

The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the *MobileDiagnost M50* when compared to the currently marketed and predicate MobileDiagnost wDR 2.0.

The wireless portable detector of the *MobileDiagnost M50* is identical to the wireless portable detector (PaxScan 4336Wv4) of the currently marketed and reference device, Varian Nexus DR™ Digital X-ray Imaging System manufactured by Varian Medical System (K161459, cleared Sept 6, 2016). Therefore, both the wireless portable detector of the *MobileDiagnost M50* and the wireless portable detector of the reference device, Varian Nexus DR™ Digital X-ray Imaging System employ identical fundamental scientific technology.

Summary of Technological Characteristics of the *MobileDiagnost M50* to the Currently Marketed and Predicate Device			
Feature	***Currently Marketed and Predicate MobileDiagnost wDR 2.0 (K141895)***	***Proposed MobileDiagnost M50***	***Discussion***
Basic Information			
Base Unit Type	Mobile X-ray unit with wireless detector	Same	No difference; thus, demonstrating SE.
Dimensions: (l x w x h) In operation max.	2550 mm x 670 mm x 2125 mm	1836 mm x 618 mm 2293 mm	The minor differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Dimensions: (l x w x h) In transport	1375 mm x 670 mm x 1980 mm	1371 mm x 618 mm x 1500 mm	The minor differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Dimensions: Source - floor distance	550 mm to 2020 mm	416 mm to 2056 mm	The minor differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Mono bloc rotation around arm axis	+/-180°	Same	No difference; thus, demonstrating SE.
Mono bloc rotation around its axis	+90° to -30°	+102° to - 49°	The minor differences in the rotation around the axis do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Mains Supply	100 VAC/110 VAC/230 VAC±10% 50 Hz/60 Hz	98-120VAC/ 195-240VAC, 50 Hz /60 Hz	The minor differences in the mains supply do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Mode of Releasing Exposure	Releasing Exposure via Hand switch or via Remote Control (Optional)	Same	No difference; thus, demonstrating SE.
Available exposure methods	Free exposure technique on film cassettes or CR systems	Same	No difference; thus, demonstrating SE.
Detector			
Type	Digital wireless flat detector	Same	No difference; thus, demonstrating SE.
Scintillator	Cesium Iodide	Gadox	The proposed *MobileDiagnost M50* uses the same wireless detector as in the

			reference device: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) (K161459), therefore there is no impact on safety and effectiveness. Thus, demonstrating SE.
Detector size	Large detector: 14" x 17" Small detector: 12" x 10"	Same: Large detector: 14" x 17"	No difference; thus, demonstrating SE.
Active area	Large detector: 13.6 " x 16.6" Small detector: 8.7 " x 11.2"	Large detector: 13.4" x 16.7"	The proposed *MobileDiagnost M50* uses the same wireless detector as in the reference device: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) (K161459), therefore there is no impact on safety and effectiveness. Thus, demonstrating SE.
Image matrix size	Large detector: 2330 x 2846 pixels Small detector: 1500 x 1920 pixels	Large detector: 2476 x 3072 pixels	The proposed *MobileDiagnost M50* uses the same wireless detector as in the reference device: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) (K161459), therefore there is no impact on safety and effectiveness.
Pixel size	148 µm	139 µm	The proposed *MobileDiagnost M50* uses the same wireless detector as in the reference device: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) (K161459), therefore there is no impact on safety and effectiveness. Thus, demonstrating SE.
Analog / Digital (A/D) conversion	16 bits	Same	No difference; thus, demonstrating SE.
Image resolution	3.38 lp/mm	3.6 lp/mm	The proposed *MobileDiagnost M50* uses the same wireless detector as in the reference device: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) (K161459), therefore there is no impact on safety and effectiveness. Thus, demonstrating SE.

Design Characteristics			
X- Ray Tube			
Type	TOSHIBA E7886X	X22	The proposed *MobileDiagnost M50* X-ray tube operates in the same manner, therefore there is no impact to safety and effectiveness. Thus, demonstrating SE.
Material	Rhenium-Tungsten, Molybdenum	Same	No difference; thus, demonstrating SE.
Maximum tube voltage	150 kVp	130 kVp	The minor differences in the maximum tube voltage does not impact safety or effectiveness of the device. Thus, demonstrating SE.
Nominal focal spot	0.7/1.3	0.8 /1.3	The minor difference in the focal spot size does not impact safety or effectiveness of the device. Thus, demonstrating SE.
Anode type	Rotating	Same	No difference; thus, demonstrating SE.
Nominal anode input power	20kW, 40kW	16kW, 32kW	The difference in the nominal anode input power does not impact safety or effectiveness of the device. Thus, demonstrating SE.
Generator			
Power	20kW, 40kW	16kW, 32kW	The minor difference in the power does not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Type	High frequency	Same	No difference; thus, demonstrating SE.
kV range	40 - 150 kV (1kV steps)	40 - 125 kV (1kV steps)	The minor difference in the maximum tube voltage does not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Milli ampere sec (mAs) range	0.1 mAs - 500 mAs	0.1 mAs - 110 mAs	The difference in the mAs range does not impact the safety or effectiveness of the device because the required detector dose can be achieved for all clinical examinations for the *MobileDiagnost M50*. Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.

Collimator			
Operation mode	Manual with light field indicator, multilayer, squared field	Same	No difference; thus, demonstrating SE.
Shape of the beam	Rectangular	Same	No difference; thus, demonstrating SE.
External Connectivity			
DICOM	DICOM compatible	Same	No difference; thus, demonstrating SE.
Software Platform			
Software	Philips *Eleva Workspot*	Same	The proposed *MobileDiagnost M50* and the currently marketed and predicate Philips MobileDiagnost wDR 2.0 both use the same software platform, the Philips Eleva Workspot with SkyFlow (K153318). Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.

Based on the information provided above, the *MobileDiagnost M50* is considered substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895, September 18, 2014) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

The *MobileDiagnost M50* complies with the following International and FDA-recognized consensus standards:

- ISO 14971, Application of risk management to medical devices
- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests
- IEC 60601-1-3, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance.- Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment.
- IEC 60601-1-6, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability
- IEC 60601-2-54, Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy

- IEC 62304, Medical Device Software - Software Life Cycle Processes.
- IEC 62366, Medical devices – Application of Usability Engineering to Medical Devices.
- ISO 10993-1, Biological Evaluation of Medical Devices. Evaluation and Testing within a Risk Management Process
- ISO 13485, Quality management for medical devices
- CFR 1020.30 Diagnostic x-ray systems and their major components.
- CFR 1020.31 Radiographic equipment.
- FDA Guidance Document, entitled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" issued September 1, 2016
- FDA Guidance Document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005
- FDA Draft Guidance Document entitled, "Pediatric Information for X-ray Imaging Device Premarket Notifications" issued May 10, 2012

Non-clinical verification and validation tests have been performed with regards to the intended use, the technical claims, requirement specifications, and the risk management results.

Non-clinical verification and validation test results demonstrate that the *MobileDiagnost M50:*

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents.
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the *MobileDiagnost M50* is substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895, September 18, 2014) in terms of safety and effectiveness.

Summary of Clinical Data:

The *MobileDiagnost M50* did not require a clinical study since substantial equivalence to the currently marketed and predicate MobileDiagnost wDR 2.0 was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing including validation; and
- Safety and effectiveness.

Furthermore, the *MobileDiagnost M50* employs an already cleared wireless detector by Varian Medical Systems (Varian PaxScan 4336Wv4 of the reference device, Varian Nexus DRTM Digital X-ray Imaging

System - K161459, cleared on 09/06/2016); therefore a clinical image study is not required.

Substantial Equivalence Conclusion:

The *MobileDiagnost M50* is substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895, September 18, 2014) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, ISO 14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54, IEC 60601-1-6, IEC 62304, IEC 62366, and ISO 10993-1.

The results of these tests demonstrate that the *MobileDiagnost M50* met the acceptance criteria and is adequate for its intended use.