Philips Medical Systems Technologies Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

April 24, 2024

Re: K240822
Trade/Device Name: Image Management V15
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 25, 2024
Received: March 25, 2024

Dear Prithul Bom:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

Submission Number *(if known)*

K240822

Device Name

Image Management V15

Indications for Use *(Describe)*

Image Management is intended to provide complete and scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve, process and display medical images and data from hospital medical imaging and information systems.
The device contains clinical applications that assist the processing, analyzing and comparing of medical images. It is a single device that integrates the review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.
The Image Management viewers are used for patient exam management by clinicians in order to access and display patient data, medical reports, medical data and medical images from different modalities including but not limited to CR, DR, CT, MR, NM, ECG, US, MG*, DBT*, OP and OPT.
The device provides wireless and portable access to medical images for remote reading or referral purposes from web browsers using current standard HTML.
*For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA 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.

510(K) SUMMARY

The Company's 510(k) Summary is provided below on the following page.

K240822

PHILIPS

510(k) SUMMARY
Philips Medical Systems Image Management Application

K240822

Company's Name and Address	Philips Medical Systems Technologies Ltd. 2 Hapnina Street, P.O. Box 46 Raanana Central, Israel 4321538 Phone: +9 7297625555
Contact Person	Shlomit Brandis Kepler Sr. Regulatory Affairs Specialist shlomit.brandiskepler@philips.com +972547790828
Date	April 23, 2024
Device Tradename	Image Management V15
Classification Name	System, Image Processing, Radiological
Product Code	LLZ
Classification	21 CFR 892.2050
Predicate Device	CARESTREAM PACS (K110919)
Reference Devices	Carestream Vue PACS (K122523) Carestream Vue PACS (K170580) Carestream Vue Motion (K151774)
Device Description and Technological Characteristics	Image Management V15 is a software based system and is intended to provide completely scalable local and wide area PACS (Picture Archiving and Communication System) solutions for hospital and related institutions/sites, which will archive, distribute, retrieve, process and display images and data from all hospital modalities and information systems. The device is to be used by trained professionals including, but not limited to, physicians and medical technicians. The device contains clinical applications that assist the processing, analyzing and comparing medical images. It is a single device that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians. IM V15 supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM (Digital Imaging and Communications in Medicine): Computed Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), Ultrasound (US), X-Ray (XR), X-Ray Angiography (XA), Positron Emission Tomography (PET), Computed Radiography (CR), Digital Radiography (DX), Digital Radiography (Abbreviation not defined by the DICOM standard) (DR),

	Radio Fluoroscopy (RF), Radiation Therapy (RT), Mammography (MG), Secondary Capture (SC), Visible Light (VL), Optical Coherence Tomography (OCT), Electrocardiogram (ECG) and Ophthalmic Photography (OP) as well as hospital/radiology information systems.
Indications for Use	Image Management is intended to provide complete and scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve, process and display medical images and data from hospital medical imaging and information systems. The device contains clinical applications that assist the processing, analyzing and comparing of medical images. It is a single device that integrates the review, dictation and reporting tools to create a productive work environment for the radiologists and physicians. The Image Management viewers are used for patient exam management by clinicians in order to access and display patient data, medical reports, medical data and medical images from different modalities including but not limited to CR, DR, CT, MR, NM, ECG, US, MG*, DBT*, OP and OPT. The device provides wireless and portable access to medical images for remote reading or referral purposes from web browsers using current standard Html. ∗For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography.
Substantial Equivalence	Image Management v15 is as safe and effective as its predicate device. Both devices have similar indications for use, technological characteristics, and principles of operation. The minor technological differences between the Image Management and its predicate device raise no new issues of safety or effectiveness. The table below summarizes the substantive feature/technological similarities and differences between the subject and predicate devices.

Table 1: Substantial Equivalence

Comparison Feature	Subject Device Philips' Image Management v15	Primary Predicate Device Carestream PACS (K110919)
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Product Code	LLZ	LLZ
Regulation Description	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulation Number	892.2050	892.2050
Indications for Use	Image Management is intended to provide complete and scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve, process and display medical images and data from hospital medical imaging and information systems. The device contains clinical applications that assist the processing, analyzing and comparing of medical images. It is a single device that integrates the review, dictation and reporting tools to create a productive work environment for the radiologists and physicians. The Image Management viewers are used for patient exam management by clinicians in order to access and display patient data, medical reports, medical data and medical images from different modalities including but not limited to CR, DR, CT, MR, NM, ECG, US, MG*, DBT*, OP and OPT. The device provides wireless and portable access to medical images for remote reading or referral purposes from web	The CARESTREAM PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians. The CARESTREAM PACS Lightweight Viewer software program is used for patient management by the referral community in order to access and display patient data, medical reports, and medical images from different modalities including CR, DR, CT, MR, NM and US after the primary reading has been completed on dedicated diagnostic workstations.

Comparison Feature	Subject Device Philips' Image Management v15	Primary Predicate Device Carestream PACS (K110919)
	browsers using current standard Html. *For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography.	The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Available Clinical Tools		
Cardiac CT Application	Yes	Yes
ECG Application	Yes	No
Cardiology (Echocardiography, XA)	Yes	Yes
Coronary Artery Analysis application	Yes	Yes
Vessel analysis application	Yes	Yes
Digital Subtraction Application	Yes	No
Calcium Scoring application	Yes	Yes
3D analysis application	Yes	Yes
Volume Matching Application	Yes	Yes
Hybrid NM viewer application	Yes	Yes
Mammography image display Application	Yes	Yes
PowerViewer application	Yes	Yes
MPR application	Yes	Yes
CT Perfusion application	Yes	No
MR Perfusion application	Yes	No
MR Diffusion application	Yes	No

Comparison Feature	Subject Device Philips' Image Management v15	Primary Predicate Device Carestream PACS (K110919)
Lesion Management Application	Yes	No
Technological Characteristics		
Supports DICOM studies received from different modality types	Yes- CT, MR, NM, US, XR, XA, PET, CR, DX, DR, RF, RT, MG, SC, VL, OPT, ECG and OP	Yes- CR, DR, CT, MR, NM, US, XR, XA, MG, PET, DX, RF, RT, MG, SC and VL
Web Diagnostic Viewer	Yes	No
OP & OPT modality support	Yes	No

In addition, the software naming convention is being introduced with a new branding, and will be titled Image Management, versus the previous use of Vue PACS.

Nonclinical Tests Performed

Performance tests have been performed on Image Management v15

Image Management v15 demonstrates compliance with the following International and FDA recognized consensus standards:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- NEMA PS 3.1-3.22 - Digital Imaging and Communications in Medicine (DICOM) Standard

Image Management V15 has been tested in accordance with Philips verification and validation processes. Verification and validation tests have been performed to address intended use, technological characteristics, requirement specifications and risk management results.

The test results in this 510(k) premarket notification demonstrate that Image Management v15 complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents, and is substantially equivalent to the primary predicate device.

Conclusion:

Based on the technological characteristics of the devices, Philips Medical Systems Technologies Ltd. believes that Image Management V15 and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.