July 15, 2025

Philips Medical Systems Nederland B.V.
Arbel Shezaf
Regulatory Affairs Manager
Veenpluis 6
5684 Pc
BEST,
NETHERLANDS

Re: K250181
Trade/Device Name: AV Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 28, 2025
Received: May 28, 2025

Dear Arbel Shezaf:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250181

Device Name

AV Viewer

Indications for Use *(Describe)*

The AV Viewer is an advanced visualization software intended to process and display images and associated data in a clinical setting.
The software displays images of different modalities and timepoints, and performs digital image processing, measurements, manipulation, quantification and communication.
The AV Viewer is not to be used 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.

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

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"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."

K250181

510(k) SUMMARY

Philips Medical Systems' AV Viewer

Company's Name and Address	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
Contact Person	Arbel Shezaf Regulatory Affairs Manager Nahum het 7, Tirat Carmel, 3508506, Israel +972544487597 arbel.shezaf@philips.com
Date	July 15, 2025
Device Trade name	AV Viewer
Classification Name	System, image processing, radiological
Product Code	LLZ
Classification	21 CFR 892.2050
Predicate Device	Philips Medical Systems' Illumeo System (K173588)
Reference Devices	• Philips Medical Systems' IntelliSpace Portal Platform (K162025) • Philips Medical Systems' IQon Spectral CT (K163711)
Device Description	AV Viewer is an advanced visualization software which processes and displays clinical images from the following modality types: CT, CBCT – CT format, Spectral CT, MR, EMR, NM, PET, SPECT, US, XA (iXR, DXR), DX, CR and RF. The main features of the AV Viewer are: • Viewing of current and prior studies • Basic image manipulation functions such as real-time zooming, scrolling, panning, windowing, and rolling/rotating. • Advanced processing tools assisting in the interpretation of clinical images, such as 2D slice view, 2D and 3D measurements, user-defined regions of interest (ROIs), 3D segmentation and editing, 3D models visualization, MPR (multi planar Reconstructions) generation, image fusion and more. • A finding dashboard used for capturing and displaying findings of the patient as an overview. • Customized workflows allow the user to create their own workflows • Tools to export customizable reports to the Radiology Information System (RIS) or PACS (Picture archiving and communication system) in different formats. AV Viewer is based on the AV Framework, an infrastructure that provides the basis for the AV Viewer and common functionalities such as: image viewing, image editing tools, measurements tools, finding dashboard. AV viewer can be hosted on multiple platforms and devices, such as Philips AVW, Philips CT/MR scanner console or on cloud.
Indications for Use	The AV Viewer is an advanced visualization software intended to process and display images and associated data in a clinical setting. The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The AV Viewer is not to be used for mammography.

Verification and Validation

Software verification and validation activities were performed to verify that the software meets the product requirements.

Verification

Verification was performed according to the verification plan.
All planned verification activities identified in the plan have been completed. Product requirement specifications were tested and found to meet the requirements.

Expert test

Expert tests have been performed in addition to the verification tests, to simulate the clinical use of the device. Use case scenarios were tested by a clinical expert and the tests passed successfully.

Validation

Validation was performed according to the validation plan to confirm the AV Viewer meets its intended use and user needs. User requirement specifications were tested and found to meet the requirements.
The validation objectives have been fulfilled, and the validation results provide evidence that the product meets its intended use and user requirements.

Bench Testing

Bench testing was performed on the measurements and segmentation algorithms to validate their performance and the correctness of the various measurement functions available in the AV Viewer.

Substantial Equivalence

The AV Viewer is as safe and effective as its predicate device. Both devices have similar intended use and indications for use, technological characteristics, and principles of operation. The minor technological differences between the AV Viewer and its predicate device raise no new issues of safety or effectiveness. In addition, other technological features available for the proposed device are already contained in the reference device, the ISPP, as detailed in Table 1 below.

Verification and validation demonstrate that the Philips Medical Systems' AV Viewer is safe and effective. Thus, the AV Viewer is substantially equivalent to the Philips Medical Systems' Illumeo System. Table 1 below summarizes the substantive feature/technological similarities and differences between the subject and predicate device.

Table 1. Substantial Equivalence

Comparison Feature	Subject Device Philips Medical Systems' AV Viewer	Predicate Device Philips Medical Systems' Illumeo System (K173588)	Reference Device Philips Medical Systems' IntelliSpace Portal Platform (K162025)	Reference Device Philips Medical Systems' IQon Spectral CT (K163711)	Comparison between the subject and predicate devices (identical/ different)
Device Class	Class II	Class II	Class II	Class II	Identical
Classification Panel	Radiology	Radiology	Radiology	Radiology	Identical
Product Code	LLZ	LLZ	LLZ	JAK	Identical
Regulation Description	Medical image management and processing system	Medical image management and processing system	Medical image management and processing system	Computed tomography x-ray system	Identical
Regulation Number	892.2050	892.2050	892.2050	892.1750	Identical
Indications for Use	The AV Viewer is an advanced visualization software intended to process and display images and associated data in a clinical setting. The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The AV Viewer is not to be used for mammography.	Illumeo system is an image management system intended to be used by trained professionals, including but not limited to radiologists. Illumeo system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing,	Philips IntelliSpace Portal Platform is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images. This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications.	The IQon Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. The IQon Spectral CT system acquires one CT dataset – composed of data from a higher-	Different

Comparison Feature	Subject Device Philips Medical Systems' AV Viewer	Predicate Device Philips Medical Systems' Illumeo System (K173588)	Reference Device Philips Medical Systems' IntelliSpace Portal Platform (K162025)	Reference Device Philips Medical Systems' IQon Spectral CT (K163711)	Comparison between the subject and predicate devices (identical/ different)
		measurement, manipulation and quantification of images, communication and storage. This device is not to be used for mammography.	Philips IntelliSpace Portal Platform is intended to be used by trained professionals, including but not limited to physicians and medical technicians. This medical device is not to be used for mammography. The device is not intended for diagnosis of lossy compressed images.	energy detected x-ray spectrum and a lower-energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number. This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of	

Comparison Feature	Subject Device Philips Medical Systems' AV Viewer	Predicate Device Philips Medical Systems' Illumeo System (K173588)	Reference Device Philips Medical Systems' IntelliSpace Portal Platform (K162025)	Reference Device Philips Medical Systems' IQon Spectral CT (K163711)	Comparison between the subject and predicate devices (identical/ different)
				anatomical and pathological structures. The system is also intended to be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society. *Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.	
Clinical Characteristics					
Intended User(s)	trained professionals, including but not limited to,	Trained professionals, including but not limited to radiologists	Trained professionals, including but not	Trained healthcare professional	Identical

Comparison Feature	Subject Device Philips Medical Systems' AV Viewer	Predicate Device Philips Medical Systems' Illumeo System (K173588)	Reference Device Philips Medical Systems' IntelliSpace Portal Platform (K162025)	Reference Device Philips Medical Systems' IQon Spectral CT (K163711)	Comparison between the subject and predicate devices (identical/ different)
	physicians and medical technicians		limited to physicians and medical technicians		
Supported imaging modalities	CT, CBCT – CT format, Spectral CT, MR, EMR, NM, PET, SPECT, US, XA, DX, CR, RF, ECG.	CT, MR, PET, SPECT, US, XA, DX, CR and RF	CT, MR, EMR, NM, PET, SPECT, US	CT, Spectral CT	Different
Technological features					
2D and 3D viewing capabilities	Yes	Yes	Yes	N/A	Identical
2D measurements (line, ROI, angle etc.)	Yes	Yes	Yes	N/A	Identical
3D Segmentation on CT and MR datasets	Yes	Yes	Yes	N/A	Identical
Cine View – sequence of images as a movie	Yes: CT, SPECT, PET, NM, MR & US	Yes, under 2D viewing capabilities	Yes: CT, SPECT, PET, NM, MR & US	N/A	Different
Finding dashboard	Yes	Yes	No	N/A	Identical
Reporting	Yes	Yes	Yes	N/A	Identical
Exporting reports and images	Yes	Yes	Yes	N/A	Identical