July 31, 2026

Hermes Medical Solutions AB
Hanne Grinaker
Chief Quality and Regulatory Affairs Officer
Strandbergsgatan 16
Stockholm, 11251
Sweden

Re: K253835
Trade/Device Name: Affinity
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ, KPS
Dated: July 17, 2026
Received: July 17, 2026

Dear Hanne Grinaker:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

NINGZHI LI -S Digitally signed by NINGZHI LI -S

For
Danial M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.

510(k) Number *(if known)*
K253835

Device Name
Affinity

Indications for Use *(Describe)*
Affinity displays, processes and analyzes nuclear medicine and radiology imaging data for investigation of physiological or pathological states. The functionality in Affinity is not intended to replace visual assessment by the intended user.

The information obtained from the images, including quantitative analysis, may be used, in conjunction with other patient-related data, to inform clinical management.

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.

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510(k) SUMMARY

The following information is provided as required by 21 CFR 807.92. K253835

Date: 21 July 2026

SUBMITTER

Name and Address: Hermes Medical Solutions AB
Strandbergsgatan 16
11251 Stockholm
Sweden

Contact Person: Hanne Grinaker
Chief Quality and Regulatory Officer
Phone: +46706604650
E-mail: qa_ra@hermesmedical.com

DEVICE

Subject Device Name:	Affinity
Device Classification:	Class II
Regulation Number:	21 CFR 892.2050 21 CFR 892.1200
Product Codes:	QIH LLZ, KPS

PREDICATE DEVICES

Primary Predicate Device Name:	Voxel Dosimetry
510(k) number:	K243919
Regulation Number:	21 CFR 892.2050
Product Codes:	QIH LLZ
Secondary Predicate Device Name:	Affinity
510(k) number:	K202882
Regulation Number:	21 CFR 892.1200
Product Code:	KPS

DEVICE DESCRIPTION

Affinity is a general image viewer which provides 2D and 3D visualization with sophisticated tools for analysis of nuclear medicine images. The tools include scrolling, zooming, panning, filtering, fusion, registration, triangulation and region drawing.

Affinity has a predesigned workflow for quantification (LLQ). The LLQ workflow provides the percentage function in each lobe by combining semi-automated CT segmentation of lung, airway, and lobar anatomy with functional image data. This data may be used to guide surgical planning for lung volume reduction surgery.

The semi-automatic segmentation algorithm implemented in Affinity is based on deep learning and is able to segment right and left kidneys, right and left lungs, liver and spleen. The results of the organ segmentation are always displayed overlaid on the CT and functional images for the user to review, and changes can be made manually to all or part of an organ region. The intended workflow is that the user shall review and correct the segmentation before approving the final result.

INTENDED USE

Affinity displays, processes and analyzes nuclear medicine and radiology imaging data for investigation of physiological or pathological states. The functionality in Affinity is not intended to replace visual assessment by the intended user.

The information obtained from the images, including quantitative analysis, may be used, in conjunction with other patient-related data, to inform clinical management.

INTENDED PATIENT POPULATION AND MEDICAL CONDITIONS

Patients of any age and gender undergoing molecular imaging investigations or radionuclide therapy.

Intended medical indication is any for which molecular imaging and radiology is performed. Examples of indications for which Affinity is used to inform clinical management include, but are not limited to, cancer diagnosis, treatment and staging, diagnosis of neurological and cardiac conditions, and monitoring of inflammation.

INTENDED USE/INDICATIONS FOR USE COMPARISON

Affinity version 5.0, version 2.0 and Voxel Dosimetry 3.1 are standalone software devices with image display, analysis and processing functionality. All devices are intended for patients of all age and gender undergoing molecular imaging investigations.
All three devices are software devices designed to be used by medical professionals in an office setting and do not involve any patient contact.

TECHNOLOGICAL COMPARISON

All three devices allow the visualization, creation, transformation, and modification of contours / regions of interest to define objects in DICOM medical image to support treatment calculation and evaluation.

Affinity 5.0 and 2.0 share common technological characteristics such as:
Support of DICOM images;
Image registration;
Management of volumes of interest;
Multimodal Image Fusion;
Quantitative Analysis

LLQ has been implemented as a separate workflow in Affinity 5.0. Affinity 5.0 and 2.0 use same information obtained from the region segmentation, but Affinity 5.0 can calculate the percentage contributions automatically compared to Affinity 2.0 where user would need to manually calculate percentages.

Affinity 5.0 and predicate device Voxel Dosimetry both include non-adaptive deep learning based semi-automatic segmentation.

Cybersecurity measures have been reinforced in Affinity 5.0 compared to its previous version 2.0.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.
Software Verification and Validation Testing:
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

Non-clinical performance testing for added features shows that the algorithms perform as expected and results were within pre-set acceptance criteria.

The organ segmentation algorithm, used either as part of LLQ or as a general segmentation tool, was validated using the Ground Truth/Gold Standard method. This validation was based on difference analysis comparing expert-drawn regions to those generated by the algorithm. The organ segmentation algorithm is identical to the algorithm in the predicate device Voxel Dosimetry.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The intended use of the subject device, Affinity (version 5.0), is considered substantially equivalent to the intended use of predicate devices Voxel Dosimetry and Affinity (version 2.0), legally marketed in the U.S. (K243919 and K202882). Non-clinical testing supports the safety of the device. Verification and validation testing demonstrate that the device performs as intended.

Affinity 5.0 is comparable to the earlier version of Affinity (version 2.0) and Voxel Dosimetry for its image display, processing and analysis functionalities. The differences in functional features do not significantly affect the safety and effectiveness of the device.

In conclusion, Hermes Medical Solutions considers Affinity (version 5.0) to be substantially equivalent to predicate devices Voxel Dosimetry (version 3.1) and Affinity (version 2.0).

Topic	Subject Device Affinity version 5.0	Primary Predicate Device Voxel Dosimetry 3.1 (K243919)	Secondary Predicate Device Affinity version 2.0 (K202882)	Equivalence
Intended Use	Affinity displays, processes and analyzes nuclear medicine and radiology imaging data for investigation of physiological or pathological states. The functionality in Affinity is not intended to replace visual assessment by the intended user. The information obtained from the images, including quantitative analysis, may be used, in conjunction with other patient-related data, to inform clinical management.	Voxel Dosimetry is a software application for nuclear medicine. Based on user input, Voxel Dosimetry calculates a volumetric map of the distribution of absorbed radiation dose on the voxel level for patients who have been administered with radioisotopes.	Affinity is a software application used to process, display, analyse and manage nuclear medicine and other medical imaging data transferred from other workstations, PACS or acquisition stations. The information acquired from viewing the images is used, in conjunction with other patient related data, for diagnosis and monitoring of disease.	Substantially Equivalent. All devices are used for displaying, processing and analyzing nuclear medicine and radiology imaging data for investigation of physiological or pathological states. Although not explicitly stated in the intended use statement, Voxel Dosimetry software application processes, displays, analyses and manages nuclear medicine imaging data transferred from other workstations, PACS or acquisition stations as part of the workflow for calculating a volumetric map of the distribution of absorbed radiation dose as described in Voxel Dosimetry labeling.
Intended Patient Population & Medical Conditions	Patients of any age and gender undergoing molecular imaging investigations or radionuclide therapy. Intended medical indication is any for which molecular imaging and radiology is performed. Examples of indications for which Affinity is used to inform clinical	Voxel Dosimetry is intended for patients of any age and gender undergoing radionuclide therapy. Voxel Dosimetry is only intended for calculating dose for FDA approved radiopharmaceuticals. Voxel Dosimetry should not be used to deviate from approved product dosing	All patients undergoing molecular imaging investigations.	Substantially Equivalent.

Topic	Subject Device Affinity version 5.0	Primary Predicate Device Voxel Dosimetry 3.1 (K243919)	Secondary Predicate Device Affinity version 2.0 (K202882)	Equivalence
	management include, but are not limited to, cancer diagnosis, treatment and staging, diagnosis of neurological and cardiac conditions, and monitoring of inflammation.	and administration instructions. Refer to the product's prescribing information for instructions.		
Intended Users	The intended users of Affinity are medical professionals trained in using the system.	The intended users of Voxel Dosimetry are medical professionals trained in using the system	The user may be an experienced physician, radiologist, medical physicist, technologist, nurse, or other operator who has been trained by an authorized distributor or by Hermes Medical Solutions. The user who makes the final report and recommendations after using this software, should be an experienced physician or radiologist.	Equivalent.
Field of Use	Nuclear medicine	Nuclear medicine	Nuclear medicine	Equivalent.
Operating System	Windows	Windows	Windows	Equivalent.
Type of Input Data	DICOM Studies: CT Image (CT) Encapsulated PDF MR Image (MR) Multi-frame True Color Secondary Capture Image (MFSC) Nuclear Medicine Image (NM) Positron Emission Tomography Image (PET) RT Structure Set (Contours) Secondary Capture Image (SC) Segmentation	DICOM Studies: CT Image (CT) Nuclear Medicine Image (NM) Positron Emission Tomography Image (PET) Segmentation	DICOM Studies : NM (Reconstructed SPECT) PET/CT MR SPECT/CT	Substantially Equivalent.

Topic	Subject Device Affinity version 5.0	Primary Predicate Device Voxel Dosimetry 3.1 (K243919)	Secondary Predicate Device Affinity version 2.0 (K202882)	Equivalence
Type of Output Data	DICOM studies: CT Image (CT) Encapsulated PDF MR Image (MR) Multi-frame True Color Secondary Capture Image (MFSC) Nuclear Medicine Image (NM) Positron Emission Tomography Image (PET) RT Dose (Dose Map) RT Structure Set (Contours) Secondary Capture Image (SC) Segmentation	DICOM studies: RT Dose (Dose Map) Secondary Capture Image (SC) Segmentation	DICOM studies: CT Image (CT) Encapsulated PDF MR Image (MR) Multi-frame True Color Secondary Capture Image (MFSC) Nuclear Medicine Image (NM) Positron Emission Tomography Image (PET) RT Dose (Dose Map) RT Structure Set (Contours) Secondary Capture Image (SC) Segmentation	Substantially Equivalent.
Supported Image Formats	DICOM	DICOM	DICOM	Equivalent
Image Display, Processing & Analysis	**General Tools** Scrolling, zooming, panning	**General Tools** Scrolling, zooming, panning	**General Tools** Scrolling, zooming, panning	Equivalent
	Region Statistics MTV TLG SUV Center-to-center (incl. Dmax)	**Region Statistics** Dose Map DVH Dose Map Statistics Table	**Region Statistics** MTV TLG SUV	Substantially Equivalent.
	Color Tables Change color tables Window/level control for CT, upper and lower threshold SPECT	**Color Tables** Change color tables Window/level control for CT, upper and lower threshold SPECT	**Color Tables** Change color tables Window/level control for CT, upper and lower threshold SPECT	Equivalent

Topic	Subject Device Affinity version 5.0	Primary Predicate Device Voxel Dosimetry 3.1 (K243919)	Secondary Predicate Device Affinity version 2.0 (K202882)	Equivalence
	Triangulation & Multi-planar views Triangulate on Transverse, Coronal and Sagittal slices View any cross section of a 3D dataset	**Triangulation & Multi-planar views** Triangulate on Transverse, Coronal and Sagittal slices	**Triangulation & Multi-planar views** Triangulate on Transverse, Coronal and Sagittal slices View any cross section of a 3D dataset	Substantially Equivalent.
	Fusion overlays Alpha blending Multi-layer fusion	**Fusion overlays** Control Alpha blending	**Fusion overlays** PET/SPECT/CT fusion with alpha blending	Equivalent.
	3D volume rendering Dose overlays 3D rendering	**3D volume rendering** Not available	**3D volume rendering** 3D rendering	Substantially Equivalent.
	Registration Semi-automatic rigid Manual registration Semi-automatic deformable registration of regions for SIRT (non-rigid)	**Registration** Semi-automatic rigid Semi-automatic deformable registration (non-rigid) Manual registration	**Registration** Semi-automatic rigid Manual registration	Substantially Equivalent.
	Segmentation manual thresholding single click paintbrush for manual segmentation semi-automatic deep learning based organ segmentation	**Segmentation** manual semi-automatic deep learning based organ segmentation manual edit of segmentation after automatic segmentation thresholding fuzzy C-means	**Segmentation** manual thresholding	Substantially Equivalent.
LLQ	Yes. Specific workflow to calculate the percentage contribution of each lung lobe to the overall lung function.	No	Yes. May be calculated using the general region tools.	Substantially Equivalent.

Topic	Subject Device Affinity version 5.0	Primary Predicate Device Voxel Dosimetry 3.1 (K243919)	Secondary Predicate Device Affinity version 2.0 (K202882)	Equivalence
Segmentation	Deep learning-based organ segmentation	Deep learning-based organ segmentation	Manual organ segmentation	Substantially Equivalent.