Hermes Medical Solutions AB
℅ Joakim Arwidson
VP Quality and Regulatory
Strandbergsgatan 16
Stockholm, 11251
SWEDEN

February 14, 2020

Re: K193152
Trade/Device Name: Affinity
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: February 7, 2020
Received: February 12, 2020

Dear Joakim Arwidson:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193152

Device Name
Affinity

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5.0 510 (k) SUMMARY

A. Submitted by:

- **Submitters name and address:**
  Hermes Medical Solutions AB
  Strandbergsgatan 16
  112 51 Stockholm
  Sweden

- **Submitters telephone number**
  Phone: +46 8 19 03 25
  E-mail: joakim.arwidson@hermesmedical.com

- **Contact person**
  Joakim Arwidson
  VP Quality and Regulatory
  Hermes Medical Solutions AB
  Strandbergsgatan 16
  112 51 Stockholm
  Sweden

- **Registration number**
  9710645

B. Preparation date:

2019-10-28

C. Proprietary/Trade name, Common name, Classification name:

- **Proprietary/Trade name**
  Affinity

- **Common name**
  Image processing systems

- **Classification name**
  Emission Computer Tomography System, Class II, 21CFR892.1200

D. Legally marketed device (predicate device):

The following legally marketed devices have been used for comparison.

- Hybrid3D (K181468) - primary
- Hermes Medical Imaging Suite (K171681) - reference

E. Description of the device that is subject of this premarket notification:

The Affinity v1.0 is a Viewer that will be the first Hermes application released on the new development platform Affinity.

The application provides 2D and 3D visualization, quantification and processing of medical images in Digital Imaging and Communications in Medicine (DICOM) format from different modalities, such

as PET/CT, MR and tomographic reconstructed SPECT from SPECT/CT. Affinity supports co-registration, with the exception of 2D images, and fusion of multiple time points with studies in the same frame of reference, different tracers, and modalities.

Affinity is developed with Microsoft Visual Studio on the .NET framework environment and designed for high throughput clinical scenarios with fast image loading and configurable workflows and layouts. In the design, emphasis has been placed on ease of use, where the user can easily access tools for 3D ROI and uptake analysis. The application supports pre-selection and automatic detection of all uptake areas within the body above a certain threshold level, by using threshold region tool. Where the user can define a threshold for any modality and unit within that modality to include all pixels of the study in a region or islands of regions.

Based on selected regions, quantification of the following parameters can be done SUV, SUVR, SUVbsa, SUVlbm, SUVbw, SUV Peak, SUV Mean, TLG and MTV.

Reference: RECIST to Percist: Evolving Considerations for PRT Response Criteria in Solid Tumors, Wahl R.L et al, Journal of Nuc Med:2009:Vol 50:122S-150S.

F. Intended use

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.

G. Technological characteristics

Comparison of the proposed device Affinity and the primary predicate device Hybrid3D (K181468) and reference device Hermes Medical Imaging Suite (K171681).

Trade Name	**Affinity**	**Hybrid3D**	**Hermes Medical Imaging Suite**	**Comparison**
510k #	**This application**	**K181468**	**K171681**	**N/A**
Operating System	Microsoft® Windows 10, 64 bit	Microsoft® Windows 7 and 10, 64 bit	Microsoft® Windows 7 and10, 64 bit	Affinity supports Windows 10 OS
Indications for use	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.	Hybrid3D is a software application that can be used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstations or acquisition stations.	HERMES Medical Imaging suite provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.	Equivalent Intended Use. Affinity also includes the specification that “The information acquired from viewing the images is used, in conjunction with other patient related data, for diagnosis and monitoring of disease.”
Patient population	All patients undergoing molecular imaging investigations.	All patients undergoing molecular imaging investigations.	All patients undergoing molecular imaging investigations.	Equivalent patient population
Software Input / Modalities PET/CT	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite

Trade Name	Affinity	Hybrid3D	Hermes Medical Imaging Suite	Comparison
SPECT/CT	Yes (tomographic reconstructed)	Yes (tomographic reconstructed)	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
MR	Yes	Yes	No	Equivalent to Hybrid3D
Anatomical sites	Whole body or constrained field of view (e.g. abdomen, brain)	Whole body or constrained field of view (e.g. abdomen, brain)	Whole body or constrained field of view (e.g. abdomen, brain)	Equivalent anatomical sites
Software Output Parameters	Methods used for quantification	Methods used for quantification	Methods used for quantification	Affinity uses equivalent algorithms for quantification.
SUV	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
SUVR	Yes	Yes (in percist criteria)	No	Equivalent to Hybrid3D
SUVbsa	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
SUVlbm	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
SUVbw	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
SUV Peak	Yes	Yes	Yes	See Note 1.
SUV Mean	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
TLG	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
MTV	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite

Trade Name	Affinity	Hybrid3D	Hermes Medical Imaging Suite	Comparison
Clinical modules				
Viewing 2D	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
Viewing 3D	Yes	Yes	Yes	Equivalent to Hybrid3D
SIRT (Selective Internal Radiation Therapy) – post treatment	No	Yes	No	No support of SIRT in Affinity
Lung Lobar Quantification	No	Yes	No	No support of Lung Lobar Quantification in Affinity
NM Processing Renogram, Gastric Emptying, DMSA, Gall Bladder EF, Lung Quantification, Sacro Illiac Joint, First Pass Shunt, Functional Gated Analysis, Brain Analysis, Thyroid Analysis, Colonic Transit, Parathyroid, Dosimetry, Oesophageal Transit, Salivary Gland, HIDA, Bone3Phase Analysis	No	No	Yes	No support of NM Processing modules in Affinity

Trade Name	Affinity	Hybrid3D	Hermes Medical Imaging Suite	Comparison
SPECT Recon-struction	No	No	Yes	Affinity can load and present tomographic reconstructed SPECT data, but not do the reconstruction itself.
Communication				
DICOM	Yes	Yes	Yes	Equivalent to Hybrid3D / Hermes medical Imaging Suite
IF (Interfile)	No	No	Yes	No support of IF (Interfile) in Affinity.

Note 1) The method for calculating SUVpeak for Affinity is exactly as described in the paper '*RECIST to Percist: Evolving Considerations for PRT Response Criteria in Solid Tumors, Wahl R.L et al, Journal of Nuc Med:2009:Vol 50:122S-150S'.* Consequently, an SUV peak will not be calculated for a volume which cannot contain a sphere of at least 1 cubic centimeter (1 cc). The primary predicate device Hybrid3D, on the other hand, uses a spherical volume for calculating SUVpeak which is as close as possible to 1 cc, so it may present an SUVpeak value even if the volume cannot contain a 1cc sphere.

H. Testing

The tests for verification and validation followed Hermes Medical Solutions AB design-controlled procedures. The Risk analysis was completed, and risk control implemented to mitigate identified hazards. The test results confirm that all the software specifications have met the acceptance criteria.

I. Substantially Equivalent/Conclusions

The clinical features supported by Affinity are equivalent in comparison to the primary predicate device Hybrid3D (K181468) and the reference device Hermes Medical Imaging Suite(K171681) as presented in 'G Technological characteristics.

When validating Affinity, comparisons were made of the parameters SUV, SUVR, SUVPeak, SUVbsa, SUVlbm, SUVMean, TLG, HU, MTV and linear measurements with the primary predicate device Hybrid3D (K181468) and the reference device Hermes Medical Imaging Suite (K171681, Hybrid Viewer). Comparison of the parameters was done with different NEMA phantom based on studies from cameras by GE, SIEMENS and Philips.

Linear Measurements on a GE CT phantom study (mm)			
#	**Hybrid 3D**	**Affinity**	**Diff (%)**
1	37.81	38.7	-2.4
2	29.04	28.9	0.5
3	22.37	23.9	-6.8
4	17.88	18.0	-0.7
5	14.16	14.5	-2.4

Linear Measurements on a Siemens CT phantom (mm)			
#	**Hybrid 3D**	**Affinity**	**Diff (%)**
1	26.87	26.7	0.6
2	27.17	27.3	-0.5
3	17.81	17.5	1.7
4	76.16	77.1	-1.2
5	188.69	188.2	0.3

Hounsfield Unit Numbers on a GE CT Phantom			
Parameter	**Hybrid 3D**	**Affinity**	**Diff (%)**
VOI1, Vol ml	2.41	2.4	0.4
VOI1, Max HU	37	41	-10.8
VOI1, Mean HU	5.52	6	-8.7
VOI2, Vol ml	1.03	1.0	2.9
VOI2, Max HU	1140	1140	0
VOL2, Mean HU	222	239	-7.7

SUV Threshold VOIs of Phillips PET study			
Parameter	**Hybrid 3D**	**Affinity**	**Diff (%)**
Vol ml	7.55	7.6	-0.7
SUV peak	15.99	16.36	-2.3
SUV max	19.3	19.3	0
SUV mean	10.5	10.5	0
TLG	79.28	79.3	0

SUV Threshold VOIs of GE PET study			
Parameter	**Hybrid 3D**	**Affinity**	**Diff (%)**
Vol ml	1.35	1.3	3.7
SUV peak	5.08	NA (volume too small)	Not applicable *See Note 1) in section 'G. Technology Characteristics'*
SUV max	7.42	7.42	0
SUV mean	5.04	5.11	-1.4
TLG	6.8	6.5	4.4

SUV Threshold VOIs of Siemens PET			
Parameter	**Hybrid 3D**	**Affinity**	**Diff (%)**
Vol ml	81.07	82.4	-1.6
SUV peak	18.07	18.28	-1.2
SUV max	24.73	24.73	0
SUV mean	12.45	12.39	0.5
TLG	1009.21	1021	-1.2

SUV values for different modes using VOI on Siemens PET study (Hybrid3D / Affinity)			
Parameter	**Hybrid 3D**	**Affinity**	**Diff (%)**
SUVBW			
Vol ml	81.07	81.1	0
SUV peak	18.07	18.28	-1.2
SUV max	24.73	24.45	1.1
SUV mean	12.45	12.39	0.5
TLG	1009.21	1009	0
SUVBSA			
Vol ml	81.07	81.1	0
SUV peak	5.16	5.22	-1.2
SUV max	7.06	7.06	0
SUV mean	3.55	3.55	0
SUV min	1.71	1.71	0
TLG	288.07	288	0

SUV values for different modes using VOI on Siemens PET study (Hybrid Viewer / Affinity)			
Parameter	**Hybrid Viewer**	**Affinity**	**Diff (%)**
SUVLBM (120)			
Vol ml	81.21	81.1	0.1
SUV peak	17.67	15.73	11
SUV max	21.29	21.29	0
SUV mean	10.69	10.72	-0.3
TLG	868.43	869	-0.1
SUVLBM (128)	**Hybrid Viewer**	**Affinity**	**Diff (%)**
Vol ml	81.21	81.1	0.1
SUV peak	17.34	15.44	11
SUV max	20.9	20.9	0
SUV mean	10.49	10.52	-0.3
TLG	852.34	853	-0.1

The quantitative assessment obtained from Affinity is in good agreement with the predicate devices Hybrid3D (K181468) and HybridViewer (Hermes Medical Imaging Suite, K171681). The biggest difference was in SUV peak compared to HybridViewer, where a difference of up to 11% was observed. The difference in SUV peak is due to that the region is manually positioned and a slight difference in the applications algorithm, where Affinity is strictly in accordance with the definition in the paper *'RECIST to Percist: Evolving Considerations for PRT Response Criteria in Solid Tumors, Wahl R.L et al, Journal of Nuc Med:2009:Vol 50:122S-150S'*.

In summary, the Affinity v1.0 described in this submission is in our opinion substantially equivalent to the predicate devices.