December 23, 2020

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

Re: K202882
    Trade/Device Name: Affinity
    Regulation Number: 21 CFR 892.1200
    Regulation Name: Emission computed tomography system
    Regulatory Class: Class II
    Product Code: KPS
    Dated: September 9, 2020
    Received: September 28, 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,

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

Indications for Use

510(k) Number *(if known)*
K202882

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.

Warning! This application is not intended to replace visual assessment of tumors. The primary purpose of the application is to provide pre-selection of lesions for visual confirmation and to provide consistency and reproducibility when assessing tumor response to treatment

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.

5.0 510 (k) SUMMARY

K202882

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:
2020-09-09

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 device have been used for comparison.

- Hybrid3D (K181468) - primary

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

Affinity can process data as whole body or constrained field of view (e.g. abdomen, brain) where scanning was performed with any of the following modalities PET/CT, MR or tomographic reconstructed SPECT/CT. The studies are read in DICOM format and if there are studies with different modalities, on the same patient, a co-registration and alignment is performed. Modifications since version 1.0 is that SUVpeak definition has changed to correlate with the results from the predicate device, together with the option to configure the SUV peak definition in order to accommodate the users need of having quantitative values that help the users in its reporting

process. Implementation of manual co-registration of images and local rigid registration, to give the user the possibility to improve the fit of two images and around specific areas of the medical image that may be of extra importance in the reporting process. Adjustments to make it possible for the user to in an easy manor create clinical workflows and layout that are configurable down to the smallest detail in order to simplify and personalize the workflow of each clinicians for maximum efficiency and accuracy in their reporting process. Optimization on the rendering engine has been performed to enable the data loading to be as low a reasonably achievable, hence reducing waiting time. Improvement have been made to the general UI to make it more intuitive for the user to work in the Affinity environment. Possibility to Create, Save and reload Region Of Interest (ROI), from Affinity itself. But it has also been updated so it can load regions created in other medical imaging software's. Possibility to create, save and reload Multi-frame secondary captures. Adjustments to make it possible for the user to in an easy manor create clinical important ROI's that are configurable to best meet the user's need to obtain relevant quantitative values that can be a guidance in the reporting process. Single click segmentation is implemented that uses the feature of threshold and split into disconnected islands, which already have verification and validation test established.

Software output - After the studies have been processed, these are presented visually in 2D or 3D for the user who can use tools to quantify the significant parameters SUV, SUVR, SUVbsa, SUVlbm, SUVbw, SUV Peak, SUV Mean, TLG and MTV.

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.

This application is not intended to replace visual assessment of tumors. The primary purpose of the application is to provide pre-selection of lesions for visual confirmation and to provide consistency and reproducibility when assessing tumor response to treatment.

G. Technological characteristics

Comparison of the proposed device Affinity and the primary predicate device Hybrid3D (K181468).

Trade Name	Affinity	Hybrid3D	Comparison
510k #	This application	K181468	N/A
Operating System	Microsoft® Windows 10, 64 bit	Microsoft® Windows 7 and 10, 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.	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.	Equivalent patient population
Software Input / Modalities PET/CT SPECT/CT MR	Yes Yes (tomographic reconstructed) Yes	Yes Yes (tomographic reconstructed) Yes	Equivalent to Hybrid3D Equivalent to Hybrid3D 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)	Equivalent anatomical sites
Software Output Parameters	Methods used for quantification	Methods used for quantification	Affinity uses equivalent algorithms for quantification.

Trade Name	Affinity	Hybrid3D	Comparison
SUV	Yes	Yes	Equivalent to Hybrid3D
SUVR	Yes	Yes (in percist criteria)	Equivalent to Hybrid3D
SUVbsa	Yes	Yes	Equivalent to Hybrid3D
SUVlbm	Yes	Yes	Equivalent to Hybrid3D
SUVbw	Yes	Yes	Equivalent to Hybrid3D
SUV Peak	Yes	Yes	Two options - Spherical kernel, option equivalent to Hybrid3D - Hottest connected, new feature in Affinity 2.0.
SUV Mean	Yes	Yes	Equivalent to Hybrid3D
TLG	Yes	Yes	Equivalent to Hybrid3D
MTV	Yes	Yes	Equivalent to Hybrid3D
Clinical modules			
Viewing 2D	Yes	Yes	Equivalent to Hybrid3D
Viewing 3D	Yes	Yes	Equivalent to Hybrid3D
SIRT (Selective Internal Radiation Therapy) – post treatment	No	Yes	No support of SIRT in Affinity
Lung Lobar Quantification	No	Yes	No support of Lung Lobar Quantification in Affinity

Trade Name	Affinity	Hybrid3D	Comparison
SPECT Recon-struction	No	No	Affinity can load and present tomographic reconstructed SPECT data, but not do the reconstruction itself.
Communication DICOM	Yes	Yes	Equivalent to Hybrid3D

Affinity is equivalent to predicate device in terms of IFU, patient population, modalities, anatomical sites and communication (DICOM). The algorithms used in the quantification of parameters are equivalent for Affinity and Hybrid3D.

H. Changes to the Software
Following modifications have been implemented since version 1.0:

- SUVpeak, the definition has changed to correlate with the results from the predicate device, together with the option to configure the SUV peak definition in order to accommodate the users need of having quantitative values that help the users in its reporting process.

- Hottest SUV peaks, as the uptake in the patient is non-homogeneous, low uptake voxels may occur right next to high uptake voxels, which will affect the SUVpeak value and may reduce its value. This has led to new methods being developed to get around these fluctuations, using a small kernel of any shape that sweeps over a region looking for the highest possible occupancy in order to find the SUV peak. This is particularly important when imaging for Hogkins Lymphoma in children, as the tumors may be very small. It is this method which has been implemented in this version.

  Hasenclever D, Kurch L. qPET - a quantitative extension of the Deauville scale to assess response in interim FDG-PET scans in lymphoma. Eur J Nucl Med Mol Imaging 2014 Jul;41(7):1301-8. doi: 10.1007/s00259-014-2715-9. Epub 2014 Mar 7.

- Implementation of manual co-registration of images and local rigid registration, to give the user the possibility to improve the fit of two images and around specific areas of the medical image that may be of extra importance in the reporting process. Adjustments to make it possible for the user to in an easy manor create clinical workflows and layout that are configurable down to the smallest detail in order to simplify and personalize the workflow of each clinicians for maximum efficiency and accuracy in their reporting process. Optimization on the rendering engine has been performed to enable the data loading to be as low a reasonably achievable, hence reducing waiting time. Improvement have been made to the general UI to make it more intuitive for the user to work in the Affinity environment. Possibility to Create, Save and reload Region Of Interest (ROI), from Affinity itself. But it has also been updated so it can load regions created in other medical imaging software's. Possibility to create, save and reload Multi-frame secondary captures. Adjustments to make it possible for the user to in an easy manor create clinical important ROI's that are configurable to best meet the user's need to obtain relevant quantitative values that can be a guidance in the reporting process.

- Single click segmentation is implemented, which uses the threshold region feature to enable the user to select one disconnected region of interest at a time with the uptake higher than the threshold value set by the user.

- The split tool function is used to separate individual regions which meet the selected criteria as it is information about these individual regions which is required clinically in order to assess tumor size/metabolic activity. Split tool has verification and validation tests established.

I. 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.

J. Substantially Equivalent/Conclusions

The proposed device Affinity and the predicate devices Hybrid 3D (K181468) have equivalent indications for use.

The proposed device uses similar technology and the fundamental concepts and operation are also the same, as described in the 510(k) submission.

Validation of the features Split tool and the SUV Hottest SUV peak tool in Affinity v2.0 has been done as described below

Summary of performance validation of intra or inter variability

The validation of Affinity v2.0 included performance testing data that demonstrates the subject device can provide reproducible tumor response assessment. The validation included 13 subjects (7 males, 6 female) that received a F18FDG-PET/CT study. Regions of interest were drawn by using the threshold tool in Affinity, with the predefined threshold value of 4 SUVbw applied to the PET study to include all voxels higher than 4 SUVbw. The regions created were split based on 1ml criteria, i.e. all disconnected regions larger than 1 ml are generated as a separate region. Brain, heart, and urinary bladder regions were deleted, based on the fact that they have no clinical importance in the pre-selection of lesions in order to perform visual confirmation and that they have normal uptake. In cases for which pathological areas where connected to non-pathological areas such as brain, heart, and urine bladder, the pathological areas were deleted and thus not included in this analysis. For every region of clinical importance, MTVs of 41% where created.

This process was repeated for each patient 5 times and with 2 different validators to establish the intra and inter variability of the threshold/split tool. For each user, the mean of all quantitative value generated for every region and patient and corresponding standard deviation were calculated, where the Standard deviation is a clear indication of the variability of the quantitative values in each region.

None of the quantitative values showed a significant change between the repeat processing of each validator and between the two validators. The variability was in all cases 0, except for in the 14-17th decimal place.

The Split tool provides quantitative parameters for tumor response assessment which from this validation displays no intra or inter variability that can have any clinical impact.

Summary of validation of the Hottest Connected SUV peak value

The introduction of the Hottest Connected region SUV Peak value provides an additional SUV peak option. The validation was performed using a synthetic software generated study containing 8 voxels, each with a different SUV value.

As there is no predicate device available for validating the SUV Hottest Connected region SUV peak values, the validation was performed by comparing the results obtained from manual calculation to those provided by Affinity, using a region placed in turn over different voxels in the synthetic study and using different values of SUV Hottest Connected Size.

In all 13 scenarios tested the results were identical.

In summary, the Affinity v2.0 described in this submission is in our opinion substantially equivalent to the predicate device.