HERMES MEDICAL SOLUTIONS AB
% Mr. Joakim Arwidson
Vice President Quality & Regulatory Affairs
Strandbergsgatan 16
STOCKHOLM SWEDEN 11251

October 25, 2018

Re: K181468
Trade/Device Name: Hybrid3D
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: August 20, 2018
Received: September 24, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.25 18:03:53 -04'00'

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K181468

Device Name
Hybrid3D

Indications for Use *(Describe)*
Hybrid3D that provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.

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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5.0 510 (k) SUMMARY

A. Submitted by:

- **Submitters name and address:**
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  112 51 Stockholm
  Sweden

- **Submitters telephone number**
  Phone: +46 8 19 03 25
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- **Contact person**
  Joakim Arwidson
  VP Quality and Regulatory
  Hermes Medical Solutions AB
  Strandbergsgatan 16
  112 51 Stockholm
  Sweden

- **Registration number**
  9710645

B. Preparation date:

2018-05-30

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

- **Proprietary/Trade name**
  Hybrid3D v3.0

- **Common name**
  Image processing systems

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

D. Legally marketed device (predicate device):

Following legally marketed device has been used for comparison.

- Hybrid3D v2.0 (K171719)

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

Hybrid3D

HERMES Hybrid3D is a reading and processing module for the advanced needs in medical imaging. It offers multi-modal (PET/CT/MR/SPECT) coregistration and interactive fusion of multiple datasets. HybridViewer 3D handles viewing and fusion of multi-sequence MRI studies with oblique orientation and allows switching between original and standard TCS view orientation as well as defining own slice directions. 3D segmentation, cropping and interpolation techniques allow

complex tasks in VOI definition and can cover cases like cavities, splitting structures into subsections or logic operations (compute intersections, merge, grow). Results can be imported and exported as DICOM and are therefore available for research in 3rd party tools. Additionally, it provides tools for advanced 3D fusion rendering of studies and VOIs.

Lung Lobe Quantification
The Lung Lobe Quantification module in Hybrid3D, introduces an efficient and automated workflow solution to accurately compute 3D lobar anatomy from CT (with or without contrast).
The workflow supports the addition of functional images (SPECT V/Q, SUV SPECT, CT iodine maps, hyperpolarized xenon MRI, etc.) to accurately relate lobar anatomy to function.
No changes have been made to Lung Lobar Quantification since the previous release.

TumorFinder
The Tumor Finder wizard provides automatic segmentation of lesions in a PET study or a combined PET/CT study pair, based on criteria relative to a background volume placed in the liver or mediastinum. This reduces the time required for tumor delineation. It also provides both visual and statistical evaluation of tumor burden, which helps with comparing follow up studies.

SIRT
Selective Internal Radionuclide Therapy (SIRT), is currently used in the treatment of liver tumors either from primary liver cancer or metastatic disease (e.g. colorectal primary cancer). The SIRT wizard provides processing for SIRT planning and verification.

F. Intended use:
Hybrid3D that provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.

Warning! The results generated by the SIRT function cannot be used to change a treatment plan after the treatment has been delivered, nor can the results be used to impact future treatment planning for any type of radiation therapy or chemotherapy. The SIRT function cannot be used for prospective treatment planning of initial treatment or retreatment with microspheres in contradiction to the labeling of Class III radiation microsphere devices.

Warning! The results from the SIRT function using the partition model for dose planning cannot be used to change a clinical Y90 SIRT treatment plan, either before or after treatment. Nor can the results be used to impact future clinical treatment planning for any type of radiation therapy or chemotherapy. The SIRT function cannot be used for prospective treatment planning, initial or retreatment, with Y90 microspheres in contradiction to the labeling of the Class III radiation microspheres devices.

G. Technological characteristics:
The proposed device Hybrid3D has the same technological characteristics as the predicate device and the same indication for use.

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 testing results supports that all the software specifications have met the acceptance criteria.

I. Substantially Equivalent/Conclusions:
The proposed device Hybrid3D v3.0 and the predicate device Hybrid 3D v2.0 (K171719) have the same indication for use.

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

The comparisons between Hybrid 3D v3.0 and Hybrid 3D v2.0 (K171719) were part of the test procedure for V3.0 and showed good results.

Validation of the Hybrid3D SIRT has been made between the calculations performed by Hybrid3D and the results from spreadsheet calculations based on the formulae published by SIRTEX for the Resin Microspheres and BTG for the Glass Theraspheres.

- **Lung Shunt** was calculated from planar images. The results for Lung Shunt were identical.
- The **Prescribed Activity** for Planning using Resin Microspheres using the BSA method were identical to 2 decimal places
- The **Activity to Implant** for Planning using Glass Microspheres using the PTV method were identical to 2 decimal places
- The Voxel Dose measured from the PET Dose Map was identical to 2 decimal places
- The Voxel Dose measured from the SPECT Dose Map varied by up to 5% because the methods used for normalization, by calculating the common field of view by the application and by the test procedure, differ slightly.
- The values for Maximum Dose and Dose at 90% Volume D90%(Gy) differ because of the inherent inaccuracy of reading values manually from the Dose Volume Histogram. The test was performed only to establish that there were no fundamental errors in the calculations.

In summary, the Hybrid3D v3.0 described in this submission is in our opinion substantially equivalent to the predicate devices.