DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2017

Hermes Medical Solutions AB
% Joakim Arwidson
Quality Manager
Skeppsbron 44
Stockholm, 11130
SWEDEN

Re: K163394
Trade/Device Name: Hybrid3D
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: March 27, 2017
Received: March 30, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163394

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

5.0 510 (k) SUMMARY

A. Submitted by:

- **Submitters name and address:**
  Hermes Medical Solutions AB
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  111 30 Stockholm
  Sweden

- **Submitters telephone number**
  Phone: +46 8 19 03 25
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- **Contact person**
  Joakim Arwidson
  Quality Manager
  Hermes Medical Solutions AB
  Skeppsbron §
  111 30 Stockholm
  Sweden

- **Registration number**
  9710645

B. Preparation date:

2016-11-22

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

- **Proprietary/Trade name**
  Hybrid3D v1.0

- **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.

- Hermes Medical Imaging Suite v5.6 (K153056)

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

The Lung Lobe Quantification module in Hybrid 3D, 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.

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.

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 and the predicate devices HERMES Medical Imaging Suite v5.6 (K153056) 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.

Comparisons were made between the module Lung Lobe Quantification in Hybrid3D v1.0 and Hermes Medical Imaging Suite v5.6 (K153056), Hybrid3D v1.0 and PMOD. The results showed a good compliance.

In summary, the Hybrid3D v1.0 described in this submission is in our opinion substantially equivalent to the predicate devices.