November 21, 2017

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

Re: K171681
Trade/Device Name: HERMES Medical Imaging Suite v5.7
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: September 29, 2017
Received: October 26, 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.

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.

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 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)*
~~TBD~~ K171681

Device Name
HERMES Medical Imaging Suite v5.7

Indications for Use *(Describe)*
HERMES Medical Imaging suite 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.

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
  Skeppsbron 44
  111 30 Stockholm
  Sweden

- **Submitters telephone number**
  Phone: +46 8 19 03 25
  Cell: +46 708 19 03 08
  Fax: +46 8 18 43 54
  E-mail: joakim.arwidson@hermesmedical.com

- **Contact person**
  Joakim Arwidson
  Quality Manager
  Hermes Medical Solutions AB
  Skeppsbron 44
  111 30 Stockholm
  Sweden

- **Registration number**
  9710645

B. Preparation date:

2017-04-18

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

- **Proprietary/Trade name**
  Hermes Medical Imaging Suite v5.7

- **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)
- Xeleris 3.1 processing and review workstation (K130884)

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

The base product design of Hermes Medical Imaging Suite v5.7 is the same as for the Hermes Medical Imaging Suite v5.6 (K153056). The following modules have been added in this applicatio to Hybrid Viewer NM Processing: Colonic Transit, Remnant Liver, Parathyroid, Dosimetry, Classic DMSA, Oesophageal Transit/Reflux, HIDA, Salivary Gland, Bone3Phase Analysis and Uniformity.

F. Intended use:
Hermes Medical Imaging suite 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 Hermes Medical Imaging Suite has the same technological characteristics as the original 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 Hermes Medical Imaging Suite v5.7 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.

The following comparative tests have been made.

- Hybrid Recon in Hermes Medical Imaging Suite v5.7 has been compared to Hybrid Recon in Medical Imaging Suite v5.6 (K153056). The comparison included 10 subjects, where each subject went through stress&rest myocardial SPECT scan with Tc99m tetrofosmin. The QPS parameters SSS, Stress volume, Stress Area, Stress Defect Area, SRS, Rest Volume, Rest Area, Rest Defect Area were calculated with the Cedar Sinai Application and compared between the applications (Pearson correlation coefficient *r* between 0.96 to 0.99).
- Hybrid Recon in Hermes Medical Imaging Suite v5.7 has been compared to Hybrid Recon in Medical Imaging Suite v5.6 (K153056). The comparison included studies on Jaszczak phantom and IEC Phantom. The results on the Jaszak Phantom showed an average error between the reconstructed and true activity concentration of -3.5 % with Hybrid Recon in Medical Imaging Suite v5.6 and -1.1 % with Hybrid Recon in Medical Imaging Suite v5.7. The results on the IEC Phantom show that the error of the reconstructed activity concentration is around 5% when the target is large enough. In small targets the partial volume effect lowers the accuracy as expected.
- Classic DMSA in HV NM Processing/Hermes Medical Imaging Suite v5.7 has been compared to the classic DMSA application in Medical Imaging Suite v5.3 (K153056). For relative function values, the maximum% difference between Classic and HybridViewer is < 5%, which represents an absolute % difference of < 2%.
- Colonic Transit in HV NM Processing/Hermes Medical Imaging Suite v5.7 has been compared to GE Xeleris 3.1 review and workstation (K130884). The results obtained from both applications were similar.
- Oesophageal Transit/Reflux Analysis in HV NM Processing/Hermes Medical Imaging Suite v5.7 has been compared to manual calculations. For the Oesophageal Transit all residual % results are in complete agreement and all Transit time values are in agreement within

0.5s. For the Oesophageal Reflux all % results agree completely and most values in counts/second agree within 5%.

- 3Phase Bone Analysis in HV NM Processing/Hermes Medical Imaging Suite v5.7 has been compared to manual calculations. The biggest difference for any value was <11%.
- HIDA in HV NM Processing/Hermes Medical Imaging Suite v5.7 was compared to manual calculations from first principles. The maximum difference between the results for all calculated values for all studies was 5%.
- Salivary Gland Analysis in HV NM Processing/Hermes Medical Imaging Suite v5.7 has been compared to manual calculations from first principles. The maximum difference between the results for all calculated values for all studies is < 0.5%

The results from the comparisons show good results and are acceptable.

In summary, the Hermes Medical Imaging Suite v5.7 described in this submission is in our opinion substantially equivalent to the predicate devices.