



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

Hermes Medical Solutions, AB  
% Mr. Joakim Arwidson  
Quality Manager  
Skeppsbron 44  
Stockholm, 111 30  
SWEDEN

June 1, 2016

Re: K153056  
Trade/Device Name: Hermes Medical Imaging Suite v5.6  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission computed tomography system  
Regulatory Class: II  
Product Code: KPS  
Dated: April 26, 2016  
Received: May 2, 2016

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. 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

**Indications for Use**

510(k) Number (if known)  
K153056

Device Name  
HERMES Medical Imaging Suite v5.6

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:

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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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Sweden
  
- **Submitters telephone number**  
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- **Contact person**  
Joakim Arwidson  
Quality Manager  
Hermes Medical Solutions AB  
Skeppsbron 44  
111 30 Stockholm  
Sweden
  
- **Registration number**  
9710645

### B. Preparation date: 2015-10-05

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

- **Proprietary/Trade name**  
Hermes Medical Imaging Suite v5.6
  
- **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 v5.5 (K142631)
- Hermes Medical Imaging Suite v5.3 (K131233)
- 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 v5.6 is the same as for the Hermes Medical Imaging Suite v5.5 (K142631). The modification includes transfer of the BRASS DatScan support and Thyroid Analysis from the old Hermes environment (Oracle ® SUN Solaris, see Hermes earlier 510k clearances) to the Hybrid Viewer NM Processing in Microsoft ® Windows.



The 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.

**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 v5.6 and the predicate devices HERMES Medical Imaging Suite v5.5 (K142631) 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 Hermes Medical Imaging Suite v5.6 and Hermes Medical Imaging Suite v5.5 (K142631), Hermes Medical Imaging Suite v5.3 (K131233) and Xeleris 3.1 processing and review workstation (K130884). The results showed a good compliance.

In summary, the Hermes Medical Imaging Suite v5.6 described in this submission is in our opinion substantially equivalent to the predicate devices.