November 8, 2024

Hermes Medical Solutions AB
Hanne Grinaker
Chief Quality and Regulatory Affairs Officer
Strandbergsgatan 16
Stockholm, 11251
Sweden

Re: K241364
Trade/Device Name: Hybrid Viewer (00859873006189)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: October 9, 2024
Received: October 9, 2024

Dear Hanne Grinaker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241364

Device Name

Hybrid Viewer (00859873006189)

Indications for Use *(Describe)*

Hybrid Viewer is a software application for nuclear medicine and radiology. Based on user input, Hybrid Viewer processes, displays and analyzes nuclear medicine and radiology imaging data and presents the result to the user. The result can be stored for future analysis.
Hybrid Viewer is equipped with dedicated workflows which have predefined settings and layouts optimized for specific nuclear medicine investigations.
The software application can be configured based on user needs.
The investigation of physiological or pathological states using measurement and analysis functionality provided by Hybrid Viewer is not intended to replace visual assessment. The information obtained from viewing and/or performing quantitative analysis on the images is used, in conjunction with other patient related data, to inform clinical management.

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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510(k) #: K241364

510(k) Summary

Prepared on: 2024-11-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hermes Medical Solutions AB
Applicant Address	Strandbergsgatan 16 Stockholm 11251 Sweden
Applicant Contact Telephone	+468190325
Applicant Contact	Ms. Grinaker Hanne
Applicant Contact Email	Hanne.grinaker@hermesmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hybrid Viewer (00859873006189)
Common Name	Emission computed tomography system
Classification Name	System, Tomography, Computed, Emission
Regulation Number	892.1200
Product Code(s)	KPS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171681	Hermes Medical Imaging Suite v5.7	KPS

Device Description Summary

21 CFR 807.92(a)(4)

Hybrid Viewer provides general tools for viewing and processing nuclear medicine and radiology images. It includes software for nuclear medicine (NM) processing studies for specific parts of the body and specific diseases using predefined workflows.
Hybrid Viewer 7.0 includes the following additional clinical features compared to Hybrid Viewer 2.8:

- Additional DICOM file support for Segmentation (SEG), RT Dose and CT Fluoroscopy
- Three energy window (TEW) correction for whole body studies
- Automatic motion correction and additional motion correction option for dual isotope
- Display quantitative SPECT studies in SUV units
- Additional NM processing workflows for:
  - Assessment of the percentage of activity which is shunted to the lung prior to Y90 microsphere treatment planning.
  - Assessment of the ratio of activity in the heart compared to the mediastinum. The workflow contains specific options for the GE Healthcare product AdreView™, a radiopharmaceutical agent used in the detection of primary or secondary pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests.
  - Assessment of the relative uptake in right, left and duplex kidneys in DMSA™ (dimercaptosuccinic acid) SPECT studies. This is an extension of an existing workflow for planar DMSA studies.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Hybrid Viewer is a software application for nuclear medicine and radiology. Based on user input, Hybrid Viewer processes, displays and analyzes nuclear medicine and radiology imaging data and presents the result to the user. The result can be stored for future analysis.
Hybrid Viewer is equipped with dedicated workflows which have predefined settings and layouts optimized for specific nuclear medicine investigations.
The software application can be configured based on user needs.
The investigation of physiological or pathological states using measurement and analysis functionality provided by Hybrid Viewer is not intended to replace visual assessment. The information obtained from viewing and/or performing quantitative analysis on the images is used, in conjunction with other patient related data, to inform clinical management.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The statement of intended use of the Hybrid Viewer 7.0 device has been rewritten for clarification but there are no underlying differences in intended use between 7.0 and that of the Hermes Medical Imaging Suite 5.7, which includes Hybrid Viewer 2.8.

Technological Comparison 21 CFR 807.92(a)(6)

There are no differences between 7.0 and the predicate device 2.8 in design, principles of operation and critical performance requirements.

For the new NM Processing workflows that include new clinical features (DMSA SPECT, Lung Liver Shunt and DICOM SEG file support) calculations have been validated using analytical verification, where the acceptance criteria for the results from using the new workflow have been based on relevant publications, referenced in the verification documents. All analytical verifications concluded that the new workflows introduced since the predicate device fulfill the acceptance criteria and are therefore safe to use.

The new features that did not include advanced calculations (support for RT Dose and CT Fluoroscopy, new motion correction options, SUV display, TEW correction and Heart Mediastinum) were verified by comparing their acceptance criteria against the test results from the scripted verification testing during the development process.

Hybrid Viewer 7.0 and predicate device Hybrid Viewer 2.8 include the same Software of Unknown Provenance items (SOUPs). In 7.0 they have been updated to the latest versions for cybersecurity.

There are differences in deployment between 7.0 and the predicate device which are:
-The Instructions for Use/User manual can be downloaded on-line in 7.0
- Licensing in 7.0 is handled as pure software so a HASP key is no longer required
- The software is deployed as a ZIP file in 7.0 instead of an installer

In conclusion, there is no change in the overall safety and effectiveness of Hybrid Viewer version 7.0 compared to predicate Hybrid Viewer version 2.8.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The conclusion of usability testing and verification and validation is that Hybrid Viewer 7.0 is substantially equivalent to the predicate device Hybrid Viewer 2.8 (which is included in Hermes Medical Imaging Suite 5.7). There are no differences in the intended use of the 7.0 device and the technological characteristics of the device related to safety and effectiveness are unchanged. No new questions of safety and effectiveness have been raised.