September 9, 2025

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

Re: K252477
Trade/Device Name: Hybrid Viewer (00859873006240)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: August 7, 2025
Received: August 7, 2025

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,

Digitally signed by Michael D. O'hara -S
Date: 2025.09.09 11:11:26 -04'00'

Michael O'Hara, Ph.D.
Deputy 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.

510(k) Number *(if known)*
K252477

Device Name
Hybrid Viewer

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 results to the user. The results 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) SUMMARY

K252477

The following information is provided as required by 21 CFR 807.92.

Date: 06 August 2025

SUBMITTER

Name and Address: Hermes Medical Solutions AB
Strandbergsgatan 16
11251 Stockholm
Sweden

Contact Person: Hanne Grinaker
Chief Quality and Regulatory Officer
Phone: +46706604650
qa_ra@hermesmedical.com

DEVICE

Subject Device Name: Hybrid Viewer
Device Classification: Class II
Regulation Number: 21 CFR 892.1200
Product Code: KPS

PREDICATE DEVICE

Predicate Device Name: Hybrid Viewer
510(k) number: K241364
Regulation Number: 21 CFR 892.1200
Product Code: KPS

DEVICE DESCRIPTION

Hybrid Viewer is a software application which provides 2D and 3D viewing, processing and analysis for nuclear medicine investigations.

The studies can be loaded from patient browsers (e.g., GOLD) or PACS (Picture Archiving and Communication System).

Hybrid Viewer provides general tools which include scrolling, zooming, panning, filtering, motion correction, fusion, registration, triangulation drawing regions of interest, synchronization of studies and performing mathematical operations. Specific investigation areas for Hybrid Viewer are Neurology (BRASS), Cardiology, Gastroenterology, Hepatology, Pneumology, Osteology and Nephrology.

INTENDED USE

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.

INTENDED PATIENT POPULATION AND MEDICAL CONDITIONS

Hybrid Viewer is intended for patients of any age and gender undergoing molecular imaging investigations.

Intended medical indication is any for which molecular imaging and radiology is performed. Examples of indications for which Hybrid Viewer may be used to inform patient management are assessment of cardiac blood flow using Tc99m in patients with cardiac disease, assessment of brain function in patients with Parkinson's' disease or dementia using Tc99m or amyloid tracers, and assessment of the difference between lung perfusion and ventilation using Tc99m tracers in order to provide a definitive diagnosis of pulmonary embolism.

TECHNOLOGICAL COMPARISON

The subject device, Hybrid Viewer (version 7.2), employs similar fundamental scientific technology as its predicate device (Hybrid Viewer version 7.0).

- Both are software-only medical devices.
- Both have the same intended use.
- Both have the same indications for use.
- Both are based on the same primary device function of image analysis.
- Both have the same use environment

The difference between version 7.2 and version 7.0 of Hybrid Viewer is the addition of the Centiloid scale for Neurology investigations. Other changes in the new version do not affect clinical workflows or risk analysis. They are bug fixes or intended to improve ease of use without changing the available results and algorithms available.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The "basic documentation" level was found to be applicable to the risk level of the software.

Non-clinical Performance Evaluation of Algorithms

Non-clinical performance testing for the addition of Centiloid shows that the algorithm performs as expected and results were within pre-set acceptance criteria. The implementation of the Centiloid scale follows the directions given in the original Centiloid publication in 2015 by William E. Klunk et al.

Correlation result after spatial normalization to MNI-152 space are as follows (Level1 as described in the original publication):
The mean SUVR YC-0 calculated value of 1.006792265 falls within the 1.0095 +/- 2% range.
The mean SUVR AD-100 calculated value of 2.072978667 falls within the 2.076 +/- 2% range.

Linear correlation of the calculated value compared to the publication are as follows (Level2 as described in the original publication):
Florbetaben correlation coefficient is 0.9915, intercept is 0.0252 and R^2=0.9956
Florbetapir correlation coefficient is 0.9648, intercept is 0.0658 and R^2=0.9907
Flutemetamol correlation coefficient is 0.9917, intercept is 0.0281 and R^2=0.9953

In conclusion, non-clinical testing supports the safety of the subject device.

SUBSTANTIAL EQUIVALENCE CONCLUSION

There is no change in the overall safety and effectiveness of Hybrid Viewer version 7.2 compared to the predicate version 7.0. The fundamental design and principles of operation remain the same.

Non-clinical testing supports the safety of the device. Verification and validation testing demonstrates that the device performs as intended.

In conclusion, Hermes Medical Solutions considers Hybrid Viewer (version 7.2) to be substantially equivalent to the predicate device Hybrid Viewer (version 7.0).