July 30, 2025

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

Re: K243919
Trade/Device Name: Voxel Dosimetry (00859873006226)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH LLZ
Dated: June 4, 2025
Received: June 4, 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: 2025.07.30 13:57:51 -04'00'

Michael D. 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)*
K243919

Device Name
Voxel Dosimetry (00859873006226)

Indications for Use *(Describe)*
Voxel Dosimetry is a software application for nuclear medicine. Based on user input, Voxel Dosimetry calculates a volumetric map of the distribution of absorbed radiation dose on the voxel level for patients who have been administered with radioisotopes.
Voxel Dosimetry presents the results to the user and the result can be stored for future analysis.

Voxel Dosimetry is intended for patients of any age and gender undergoing radionuclide therapy.

Voxel Dosimetry is only intended for calculating dose for FDA approved radiopharmaceuticals.
Voxel Dosimetry should not be used to deviate from approved product dosing and administration instructions.
Refer to the product's prescribing information for instructions.

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."

510(k) SUMMARY

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

Date: 25 July 2025

SUBMITTER

Name and Address: Hermes Medical Solutions AB
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11251 Stockholm
Sweden

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

DEVICE

Subject Device Name: Voxel Dosimetry
Device Classification: Class II
Regulation Number: 21 CFR 892.2050
Product Code: LLZ
QIH

PREDICATE DEVICE

Predicate Device Name: Voxel Dosimetry
510(k) number: K191216
Regulation Number: 21 CFR 892.2050
Product Code: LLZ

DEVICE DESCRIPTION

Voxel Dosimetry is a standalone software application designed to assist the user in absorbed dose calculations at voxel level using a single volumetric image or a time series of images taken after the treatment dose is given to the patient.

Voxel Dosimetry can perform absorbed dose calculations at an organ level (VOI) for right and left kidneys, right and left lungs, liver and spleen, utilizing deep learning based semi-automatic segmentation. The results of the organ segmentation are always displayed overlaid on the CT and functional images for the user to review, and changes can be made manually to all or part of an organ region. The intended workflow is that the user shall review and correct the segmentation before approving the final result.

INTENDED USE

Voxel Dosimetry is a software application for nuclear medicine. Based on user input, Voxel Dosimetry calculates a volumetric map of the distribution of absorbed radiation dose on the voxel level for patients who have been administered with radioisotopes. Voxel Dosimetry presents the results to the user and the result can be stored for future analysis.

INDICATIONS FOR USE

Voxel Dosimetry is intended for patients of any age and gender undergoing radionuclide therapy.

Voxel Dosimetry is only intended for calculating dose for FDA approved radiopharmaceuticals. Voxel Dosimetry should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

TECHNOLOGICAL COMPARISON

The subject device, Voxel Dosimetry (version 3.1), employs similar fundamental scientific technology as its predicate device (Voxel Dosimetry version 1.0).

- Both are software-only medical devices.
- The Intended use compared to version 1.0 (predicate device), has been re-phrased, but there are no underlying differences in intended purpose since version 1.0 of Voxel Dosimetry.
- Both have the same indications for use.
- Both are based on the same primary device function of absorbed dose calculation at voxel level.
- Both have the same use environment

The following technological differences exist between version 3.1 of Voxel Dosimetry compared to version 1.0:

- Non-rigid registration
- Semi-automatic organ segmentation
- Lesion segmentation
- Single time point dose calculation
- Organ based dose calculation
- Dose calculation implementation in GPU using CUDA

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 added features shows that the algorithms perform as expected and results were within pre-set acceptance criteria. The features were tested against state-of-the-art devices or by comparison with other established methods.

Acceptance criteria for all new features use published statistical methods or are comparison criteria which are consistent with published studies.

Non-rigid alignment was added to the Align workflow and can be used to fine-tune the rigid alignment for CT studies. Testing based on comparison using a manual method shows that results meet the acceptance criteria.

Semi-automatic organ segmentation using deep learning was added to the VOI workflow and tested against manual segmentation. Testing shows that the results meet the acceptance criteria.

Lesion (region of interest) segmentation was added to the VOI workflow. Testing of reproducibility shows that the results meet the acceptance criteria. Lesion contours can be reviewed and corrected as needed by the user.

The option to process single point studies was added to the Dose workflow. Testing of time activity curve integration of these studies, based on comparison with a scientific computing language widely referenced in medical publications, shows that the results meet the acceptance criteria.

Dose calculation implementation in GPU using CUDA was added to the Dose workflow in Voxel Dosimetry

3.1. Testing to compare CPU and GPU implementations shows that the results meet the acceptance criteria.

Organ based dose calculation was added to the Dose workflow. Testing to compare the results with a state-of-the-art device shows that the results meet the acceptance criteria.

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 Voxel Dosimetry version 3.1 compared to the predicate version 1.0. There are new functionalities compared to the predicate device, but 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 Voxel Dosimetry (version 3.1) to be substantially equivalent to the predicate device Voxel Dosimetry (version 1.0).