



January 13, 2026

Spectrum Dynamics Medical, Ltd.
Igor Naroditsky
Vice President, Quality and Regulatory Affairs
22 Bareket St. North Industrial Park
Caesarea, 3079837
Israel

Re: K254001

Trade/Device Name: VERITON CT 300 Series Digital SPECT/CT System (VERITON CT 316/364)
VERITON CT 400 Series Digital SPECT/CT System (VERITON CT 416/464)

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission computed tomography system

Regulatory Class: Class II

Product Code: KPS, JAK, LLZ, QIH

Dated: December 15, 2025

Received: December 15, 2025

Dear Igor Naroditsky:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254001

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Please provide the device trade name(s).

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VERITON CT 300 Series Digital SPECT/CT System (VERITON CT 316/364)
VERITON CT 400 Series Digital SPECT/CT System (VERITON CT 416/464)

Please provide your Indications for Use below.

?

Spectrum Dynamics Medical's VERITON system is intended for use by trained healthcare professionals to aid in the detection, localization, diagnosis, staging and restaging of lesions, diseases, and organ function. For evaluating diseases and disorders such as cardiovascular disease, neurological disorders, and trauma. System outcomes can be used to plan, guide, and monitor therapy.

SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques: whole body and tomographic imaging.

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data (anatomy) from either the same axial plane taken at different angles or spiral planes take at different angles.

SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (As Required by 21 CFR 807.92)

510(k) Number: K254001

Date of submission: December 12, 2025

Submitter: Spectrum Dynamics Medical Ltd.
22 Bareket St. North Industrial Park
Caesarea, Israel 3079837.

Submitter Contact: Mr. Igor Naroditsky, VP QA/RA
Tel: + (972) 73-737-4548
Email: igorn@spectrum-dynamics.com

Device Trade Name: VERITON CT 300 Series Digital SPECT/CT System (VERITON CT 316/364)
VERITON CT 400 Series Digital SPECT/CT System (VERITON CT 416/464)

Classification Panel: Radiology

Regulation: 21 CFR 892.1200 - Emission Computed Tomography

Product Codes: KPS, JAK, LLZ, QIH (Class II)

Common Name/Classification: Single Photon Emission Computed Tomography (SPECT)/Computed Tomography (CT) system

Predicate device:

Predicate Device: VERITON CT 300/400 Series Digital SPECT/CT System

Sponsor: Spectrum Dynamics Medical Ltd.

510(k) Number: K230600

The predicate has not been withdrawn or found to be unsafe or ineffective.

Device Description:

The VERITON CT 300/400 Digital SPECT/CT System is a hybrid imaging system combining SPECT and multi-slice CT imaging for anatomical and functional assessment. The subject device introduces a software-only modification to the cleared system by adding VERITAS.AI Noise Reduction, an optional deep-learning post-processing feature integrated into the VERITON-CT Operator's Console. The AI module uses a

convolutional neural network (CNN) to reduce noise in reconstructed SPECT images without altering acquisition parameters, hardware performance, radiation-emitting components, or quantitative reconstruction values.

Three workflow-specific models are included: Bone-IQ.AI, Thera-IQ.AI, and MIBG-IQ.AI.

All hardware, electrical safety characteristics, EMC characteristics, and imaging subsystems are unchanged from the predicate device.

Indications for Use:

Spectrum Dynamics Medical's VERITON system is intended for use by trained healthcare professionals to aid in the detection, localization, diagnosis, staging and restaging of lesions, diseases, and organ function. For evaluating diseases and disorders such as cardiovascular disease, neurological disorders, and trauma. System outcomes can be used to plan, guide, and monitor therapy. SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques: whole body and tomographic imaging. CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data (anatomy) from either the same axial plane taken at different angles or spiral planes take at different angles. SPECT +CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

Summary of Technological Characteristics

The technological characteristics of the subject and predicate devices are identical except for the addition of the optional VERITAS.AI Noise Reduction feature.

The AI module:

- Operates only on reconstructed SPECT images
- Produces secondary enhanced images while preserving original images
- Does not alter quantitative values, raw data, or dosimetry
- Requires no changes to system hardware, acquisition workflow, or operator procedures

The modification does not introduce new materials, new energy sources, or new diagnostic functions

Note: This device should not be used to deviate from the approved dosing and administration instructions; see SPECT drug prescribing information for additional information.

Summary of Performance Data

Non-Clinical Testing

Software Version 2.5.0 was developed under an IEC 62304 Class B SDLC and evaluated per FDA software and cybersecurity guidance, IEC 81001-5-1, AAMI TIR57, AAMI TIR97, ISO 14971, and IEC 62366-1.

Verification and validation activities included:

- Software unit, integration, and system testing
- AI model performance testing
- Phantom-based image-quality testing (SNR, uniformity, resolution, detectability)
- Cybersecurity risk assessment and SBOM vulnerability analysis
- Usability and workflow testing
- Diagnostic-quality assessment by a board-certified radiologist

All results met predefined acceptance criteria.

VERITAS. AI Validation

Summary Test Statistics, Acceptance Criteria, and Results

Signal Preservation: Lesion maximum voxel intensity (Bq/ml) was compared between NR-processed and non-processed images using linear regression.

Results:

- Bone (Tc-99m): $R^2 = 0.99$, Slope = 0.94
- Soft Tissue (Lu-177 and mIBG): $R^2 = 0.99$, Slope = 0.99
- Pass criteria: $R^2 > 0.8$, Slope 0.9–1.1 (pre-specified)
- Mean difference: -6% (Bone), -0.7% (Soft Tissue)

Noise Suppression:

Background SD/Mean ratio reduced by 28% (Bone) and 20% (Soft Tissue) after NR processing.

Blinded Visual Assessment:

- Two board-certified nuclear medicine physicians independently rated images (noise, artifacts, overall IQ, diagnostic confidence) on a 5-point Likert scale.
- NR images were consistently rated as “similar” or “better” than non-processed (means 3.0–4.9/5 across tracers).
- Inter-reader agreement: 92–100% across all domains.

Number of Individual Patients

- Total patients in dataset: 106 (multi-center, international)
- Evaluation set: 30 patients (not used in training/tuning), 13 Bone (Tc-99m), 17 Soft Tissue (10 Lu-177, 7 mIBG)

Number of Samples and Relationship

- Total SPECT bed-position (BP) scans: 369 (from 106 patients)
- Each patient contributed multiple BP scans (Bone: typically, 3 BPs; Lu-177: typically, 6 BPs).
- Evaluation set: 30 images from 30 patients (one per patient).

Demographic Distribution

- Gender: 44 females / 62 males
- Age: 66.5 ± 21.6 years (overall); 45.6 ± 26.8 years (evaluation set)
- BMI: 24.9 ± 4.2 (overall); 24.3 ± 3.8 (evaluation set)
- Ethnicity: Ethnicity does not affect SPECT image physics or algorithm performance. Image quality depends on tracer biodistribution, acquisition protocol, and patient size (BMI), not genetic factors. Including age, gender, and BMI ensures clinical variability is covered.

Clinical Subgroups and Confounders

Clinical subgroups: Bone (Tc-99m), Soft Tissue (Lu-177, mIBG)

Confounders addressed:

- Detected counts/statistics (primary driver of noise)
- Motion artifacts and patient positioning QC-screened at acquisition
- Daily QC for detector performance

Equipment and Protocols

System: VERITON-CT whole-body SPECT/CT, software v2.5.0

Acquisition:

- Bone: 3 BPs (head-to-thighs)
- Lu-177: 6 BPs (head-to-toes)

Reconstruction: OSEM, 2.46 mm^3 voxels, standard parameters per tracer

QC: Daily NEMA NU-1:2023 compliance

Reference Standard (“Truthing”) and Inter-Observer Agreement

- Reference standard: Non-processed clinical images (paired with NR-processed for direct comparison)
- Lesion ROIs: Defined in MIM (K233620) for quantitative analysis

- Visual assessment: Two independent, board-certified nuclear medicine physicians
- Inter-reader agreement: 92–100% (kappa analysis)

Independence of Test Data from Training Data

Patient-level split:

- 76 patients (39 Bone, 37 Lu-177) for training/tuning
- 30 patients (13 Bone, 17 Soft Tissue) held out for evaluation only

No overlap between training/tuning and evaluation sets

EMC / Electrical Safety

EMC and electrical safety retesting were not required, as the modification is software-only and does not affect emissions, immunity, or safety-related hardware functions. Predicate compliance to IEC 60601-1 and IEC 60601-1-2 remains applicable.

No clinical testing was required to support substantial equivalence.

Substantial Equivalence Discussion

The subject device has the same intended use, principles of operation, hardware configuration, and fundamental scientific technology as the predicate device. The addition of the optional VERITAS.AI Noise Reduction feature does not alter performance characteristics related to safety or effectiveness. Verification and validation demonstrate that the modified device performs as intended and does not raise new questions of safety or effectiveness.

Conclusion

Based on the submitted information, including device description, technological comparison, non-clinical performance testing, and risk management, the VERITON® CT 300/400 Digital SPECT/CT System with Software Version 2.5.0 is as safe, as effective, and substantially equivalent to the predicate device (K230600).