December 30, 2025

Spectrum Dynamics Medical, Ltd.
Igor Naroditsky
VP QA/RA
22 Bareket St. N. Industrial Park
Caesarea, 3079837
Israel

Re: K253532
Trade/Device Name: TruSPECT Processing Station
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: November 13, 2025
Received: November 13, 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.	K253532

Please provide the device trade name(s).

TruSPECT Processing Station

Please provide your Indications for Use below.

TruSPECT is intended for acceptance, transfer, display, storage, and processing of images for detection of radioisotope tracer uptakes in the patient's body. The device using various processing modes supported by the various clinical applications and various features designed to enhance image quality. The emission computerized tomography data can be coupled with registered and/or fused CT/MR scans and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes. The acquired tomographic image may undergo emission-based attenuation correction.
Visualization tools include segmentation, colour coding, and polar maps. Analysis tools include Quantitative Perfusion SPECT (QPS), Quantitative Gated SPECT (QGS) and Quantitative Blood Pool Gated SPECT (QBS) measurements, Multi Gated Acquisition (MUGA) and Heart-to-Mediastinum activity ratio (H/M).
The system also includes reporting tools for formatting findings and user selected areas of interest. It is capable of processing and displaying the acquired information in traditional formats, as well as in three-dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the imaged organs.
TruSPECT is based on Windows operating system. Due to special customer requirements and the clinical focus the TruSPECT can be configured with different combinations of Windows OS based software options and clinical applications which are intended to assist the physician in diagnosis and/or treatment planning. This includes commercially available post-processing software packages.
TruSPECT is a processing workstation primarily intended for, but not limited to cardiac applications. The workstation can be integrated with the D-SPECT cardiac scanner system or used as a standalone post-processing station.

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)

510(k) SUMMARY

510(k) Number: K253532

Date of submission:	Nov 25, 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) 54-438-4386 Fax: + (972) 73-737-4502 Email: igorn@spectrum-dynamics.com
Device Trade Name:	TruSPECT Processing Station
Common Name/Classification:	Automated Radiological Image Processing Software Medical image management and processing system
Class:	II
Product Code:	QIH, LLZ
Classification Panel:	Radiology
Regulation No:	892.2050

Marketed Devices:

The TruSPECT Processing Station is a software-only medical device previously cleared under 510(k) K212230. The current submission introduces the TruClear AI module, a post-processing artificial intelligence algorithm designed to reduce noise in low-count D-SPECT Tc-99m myocardial perfusion imaging (MPI) studies. All other device functions, technological characteristics, and system features are the same as the predicate device.

Predicate device:

TruSPECT Processing Station (K212230)

Device Description:

The TruSPECT Processing Station is a software-only medical device (SaMD) designed to operate on a dedicated, high-performance computer platform. It is distributed as pre-installed medical imaging software intended to support image visualization, quantitation, analysis, and comparison across multiple imaging modalities and acquisition time points. The software supports both functional imaging modalities, such as Single Photon Emission Computed Tomography (SPECT) and Nuclear Medicine (NM), as well as anatomical imaging modalities, such as Computed Tomography (CT).

The system enables integration, display, and analysis of multimodal image datasets to assist qualified healthcare professionals in image review and interpretation within the clinical workflow. The software is intended for use by trained medical professionals and assists in image assessment for various clinical applications, including but not limited to cardiology, electrophysiology, and organ function evaluation. The software does not perform automated diagnosis and does not replace the clinical judgment of the user.

The TruSPECT software operates on the Microsoft Windows® operating system and can be configured with various software modules and clinical applications according to user requirements and intended use. The configuration may include proprietary Spectrum Dynamics modules and commercially available third-party post-processing software packages operating within the TruSPECT framework.

The modified TruSPECT system integrates the TruClear AI application as part of its software suite. The TruClear AI module is a software-based image processing component designed to assist in the enhancement of SPECT image data acquired on the TruSPECT system. The module operates within the existing reconstruction and review workflow and does not alter the system's intended use, indications for use, or fundamental technology.

Verification and validation activities were performed to confirm that the addition of the TruClear AI module functions as intended and that overall system performance remains consistent with the previously cleared TruSPECT configuration. These activities included performance evaluations using simulated phantom datasets and representative clinical image data, conducted in accordance with FDA guidance. The results demonstrated that the modified TruSPECT system incorporating TruClear AI meets all predefined performance specifications and continues to operate within the parameters of its intended clinical use.

Indications for Use:

TruSPECT is intended for acceptance, transfer, display, storage, and processing of images for detection of radioisotope tracer uptakes in the patient's body. The device using various processing modes supported by the various clinical applications and various features designed to enhance image quality. The emission computerized tomography data can be coupled with registered and/or fused CT/MR scans and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes. The acquired tomographic image may undergo emission-based attenuation correction.

Visualization tools include segmentation, colour coding, and polar maps. Analysis tools include Quantitative Perfusion SPECT (QPS), Quantitative Gated SPECT (QGS) and Quantitative Blood Pool Gated SPECT (QBS) measurements, Multi Gated Acquisition (MUGA) and Heart-to-Mediastinum activity ratio (H/M).

The system also includes reporting tools for formatting findings and user selected areas of interest. It is capable of processing and displaying the acquired information in traditional formats, as well as in three-dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the imaged organs.

TruSPECT is based on Windows operating system. Due to special customer requirements and the clinical focus the TruSPECT can be configured with different combinations of Windows OS based software options and clinical applications which are intended to assist the physician in diagnosis and/or treatment planning. This includes commercially available post-processing software packages.

TruSPECT is a processing workstation primarily intended for, but not limited to cardiac applications. The workstation can be integrated with the D-SPECT cardiac scanner system or used as a standalone post-processing station.

Technological characteristics:

The TruSPECT Processing Station maintains the same fundamental technological characteristics as its predicate device. The system’s basic functionality for processing and reviewing nuclear medicine (NM) and associated computed tomography (CT) images remains unchanged. Core capabilities include manual and automatic segmentation tools that enable users to present, localize, and quantify the distribution of radionuclide tracers and anatomical structures for diagnostic purposes.

The modified TruSPECT system introduces an additional application focused on a specific imaging attenuation technique that builds upon the system’s established functionality. TruSPECT enhances existing applications to improve workflow efficiency by incorporating both pre-trained

neural networks within the iterative reconstruction process and traditional image processing algorithms. These modifications do not alter the system's intended use, indications for use, or fundamental software architecture. Technological changes are limited to performance improvements achieved through algorithmic optimization and the integration of the new TruClear AI post-processing capability.

Characteristic	Predicate device	Proposed device
Workflow	Manual and automated processes, pre-trained neural networks in iterative reconstruction, traditional algorithms	Same
AI utilization	Non-adaptive machine learning algorithms trained with clinical data	Same
Hardware	Preinstalled on Spectrum Dynamics workstation or loaded onto customer's workstation meeting specifications	Same

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

The proposed TruSPECT Processing Station incorporates identical or equivalent technological characteristics to those of its predicate device. Modifications do not alter the fundamental software architecture, intended use, or mode of operation. Any technological differences have been fully assessed and do not raise new or different questions of safety or effectiveness. The software was developed, verified, and validated in accordance with Spectrum Dynamics Medical's Quality Management System (QMS) and compliant with IEC 62304 and applicable FDA guidance documents.

Preclinical Validation

The proposed TruSPECT Processing Station and its associated applications underwent comprehensive verification and validation in accordance with Spectrum Dynamics Medical's QMS. All design, performance, and safety testing demonstrated that the system meets its defined specifications and functions as intended. Testing confirmed compliance with relevant standards, including NEMA PS3.1–3.20 and IEC 62304, and was performed under procedures consistent with 21 CFR 820 and ISO 13485. Evaluation activities included software verification, system integration and performance testing, simulated-use testing, and risk-based assessments. No new safety concerns or performance risks were identified. The results confirmed that the TruSPECT system continues to perform within its intended specifications and maintains the same level of safety and effectiveness as the predicate device.

Clinical Validation Acceptance Criteria (Prespecified)

Parameter	Bland Altman Mean (bias)	Bland Altman SD (precision)	Regression r (min)	Slope (range)	Intercept (limit)
LVEF	±3%	≤ 4%	> 0.8	0.9 – 1.1	± 10%
EDV	± 5 ml	≤ 8 ml	> 0.8	0.9 – 1.1	± 10 ml
Perfusion Volume	± 5 ml	≤ 8 ml	> 0.8	0.9 – 1.1	± 10 ml
TPD	± 3%	≤ 5%	> 0.8	0.9 – 1.1	± 10%

Note: Criteria are conservative relative to published test retest and inter software variability.

AI-Based Algorithm Validation (TruClear.AI Noise Reduction)

TruClear.AI is an artificial intelligence–based post-processing module integrated into the TruSPECT Processing Station for denoising low-count D-SPECT myocardial perfusion SPECT images. The device modification consists of adding this AI module to the previously cleared system (K212230), with all other device functions and intended use unchanged.

Validation Approach and Substantial Equivalence Basis:
Validation was performed using a multi-center, retrospective dataset of 352 patients (137 female, 215 male; mean age 65.4±12.4 years; BMI 29.4±6.4) from three hospitals in the UK and Germany. The held-out test set included 24 patients (8 female, 16 male). The algorithm was trained and evaluated using independent datasets, ensuring that test data were not used for training or tuning.

Reference Standard ("Truthing") and Inter-Observer Agreement:
The reference standard was the clinical routine high-count SPECT image (~1.0 MCounts) acquired under standard D-SPECT protocols. Quantitative evaluation used FDA-cleared Cedars-Sinai QPS/QGS to derive perfusion and functional parameters (TPD, volume, EDV, LVEF). Two independent, board-certified nuclear medicine physicians visually compared denoised low-count images to the high-count reference using a 5-point Likert scale; inter-observer percent agreement after dichotomization (scores ≥3 vs <3) was 97–100% across key metrics.

Independence of Test Data from Training Data:
Datasets were split at the patient level into nonoverlapping training/tuning and held-out test sets. The held-out test set (24 patients; 74 images) was used only for final evaluation, no patients, images, or derived patches from this set were used for training or tuning. Patches were generated exclusively from training/tuning images; test images remained intact, and all reader and QPS/QGS analyses were performed on the held-out test set.

Key Performance Results (Held-Out Test):
Strong correlation between denoised and reference images for perfusion and functional parameters (e.g., LVEF r=0.94, EDV r=0.98, TPD r=0.98). Bland–Altman analyses showed mean differences within pre-specified acceptance criteria. Visual similarity ratings indicated denoised images were 'similar' to reference, consistent with high inter-reader agreement.

Demographics and Relevance of Ethnicity:
The validation cohort included a range of BMIs (including obese cases), both rest and stress studies, and upright and supine acquisitions. Race/ethnicity was not recorded; for myocardial perfusion SPECT noise-reduction performance, algorithm behaviour is driven by physical/physiological imaging characteristics (count statistics, anatomy, acquisition protocol) that are not known to be affected by patient ethnicity. Accordingly, ethnicity is not considered a relevant variable for this technical image-quality and quantitative performance evaluation.

Conclusion:
Across reader studies and quantitative analyses, TruClear.AI demonstrates substantial concordance between denoised low-count outputs and clinical routine high-count references, meeting pre-specified acceptance criteria. The device maintains the intended use, operating principles, and safety/effectiveness profile of the predicate (K212230), and the AI module does not raise new questions of safety or effectiveness supporting the basis for a determination of substantial equivalence.

Clinical Evaluation

Clinical studies were not required to support the determination of substantial equivalence. Performance of the TruClear AI reconstruction module was evaluated using representative clinical datasets to confirm the module's ability to enhance image quality and reduce noise while maintaining diagnostic integrity. Evaluations were conducted by qualified Nuclear Medicine (NM) physicists and physicians, who independently reviewed reconstructed images and rated them using a 5-point Likert scale. Results demonstrated that the algorithm's performance is consistent with standard image quality expectations and supports the intended clinical use without altering diagnostic interpretation. These findings confirm that the addition of TruClear AI does not introduce new safety or effectiveness concerns.

Substantial Equivalence

The proposed TruSPECT Processing Station has the same intended use and similar technological characteristics as the predicate device. Differences in design or implementation do not raise new or different questions of safety or effectiveness. Key factors supporting substantial equivalence include:

- The Indications for Use are unchanged from the predicate device.
- The technological characteristics are identical or equivalent to those of the predicate.
- Verification and validation testing confirmed compliance with performance requirements.
- The software development and validation were conducted under a quality system in accordance with recognized standards and FDA expectations for a Moderate level of concern software device.

Conclusion:

Based on compliance with applicable standards, successful completion of verification and validation testing, and adherence to Spectrum Dynamics Medical's quality system, the company concludes that the TruSPECT Processing Station, including the TruClear AI functionality, is substantially equivalent to the predicate device, the TruSPECT Processing Station (K212230). The device is therefore considered safe and effective for its intended use.