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

August 16, 2021

Re: K212230
Trade/Device Name: TruSPECT Radiological Image 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: July 10, 2021
Received: July 16, 2021

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 (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 located 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.

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

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

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k212230

Device Name
TruSPECT Radiological Image Processing Station

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY

510(k) Number: k212203

Date of submission:	July 10, 2021
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**
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 Spectrum Dynamics TruSPECT is a modification to the D-SPECT® Processing and Reviewing Workstation (K160120). The modification is the TruCorr, an image attenuation correction method which integrates pre-trained neural networks in the iteration reconstruction process to control image attenuation. ThruCorr aids as an alternative to the current image attenuation correction algorithm based on CT image, which is still available on the proposed devices.

All other features in the system are the same as in the D-SPECT Processing and Reviewing Workstation (K160120) and have the same functionality, safety, and performance.

Predicate device:

D-SPECT® Processing and Reviewing Workstation (K160120)

Device Description:

The TruSPECT is a Nuclear Medicine Software system designed for nuclear medicine images' post processing and further review procedures for detection of the radioisotope tracer uptake in the patient's body. Thus, using a variety of post processing features oriented to specific clinical applications.

SUMO Workflow enables visual evaluation and assessment of the sympathetic innervation system of the heart by quantification of uptake ratios between regions of interest, identifying discreet uptake areas of AdreViewtm (Iobenguane I^{123} Injection) or similar agents within the heart. The results generated by the SUMO workflow can be displayed on the D-SPECT processing station and additionally, can be exported to EP systems. It can also be used by the physician to aid in ablation treatment planning by electrophysiologists.

D-SPECT Dynamic CFR is a workflow for visualization, evaluation, and quantification of specific areas of attention. 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 providing quantitative blood flow measurements of SPECT images. The application provides visualization and measurement tools for both qualitative and quantitative visualization and input data evaluation. It provides automated and manual tools for orientation and segmentation of the myocardium. The software calculates myocardial blood flow measurements and provides tools, such as a database comparison workflow, to the clinician to evaluate these outcomes.

TruSPECT CT based Attenuation Correction (CTAC) is an application that removes soft tissue artifacts from SPECT images. The goal is to minimize the impact of attenuation to provide more consistent and reliable reading images. The CT Attenuation Correction (CTAC) uses a second form of imaging (CT) to develop a density map of each patient and correct the SPECT image accordingly.

TruCorr enhances the user's ability to visualize the acquired information (by way of a single clear image) - thus optimizing what would otherwise be a disjointed visual comparison. It is an Emission Based attenuation correction application using the deep learning model which was trained to directly estimate attenuation corrected SPECT images from non-attenuation corrected ones without the use of any anatomical images.

Intended 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 characteristic:

TruSPECT 's basic functionality for processing and reviewing nuclear medicine and associated CT images has not changed from its predicate. This capability includes manual and automatic segmentation to present, localize and/or quantify the distribution of radionuclide tracers and anatomical structures in patients for diagnostic purposes. Most of these features are designed to simplify users' workflows.

TruSPECT introduces a new application that focused on specific imaging attenuation technique, using this basic functionality proposed TruSPECT also enhances existing applications to improve

their workflow efficiency using both pre-trained neural networks in the iteration reconstruction process and traditional algorithms.

Characteristic	Predicate device	Proposed device
Workflow	Uses both, manual and automated processes.	Continues use both, manual and automated processes. Also includes a new, pre-trained neural networks in the iteration reconstruction process and and traditional algorithms
AI utilization	Does not contain any AI processes/algorithms	Use artificial intelligence including nonadaptive machine learning algorithms trained with clinical and/or artificial data
Hardware Needed to Support proposed station	Offered as preinstalled on Spectrum Dynamics workstation.	Offered as preinstalled on Spectrum Dynamics workstation or as software that can be loaded onto the customer's workstation that meets specification.

The Proposed TruSPECT has identical or equivalent technological characteristics as its predicate devices. The changes and the different technological characteristics do not raise new or different questions of safety and effectiveness. The software was developed, verified, and validated under Spectrum Dynamics Medical's QMS including software development lifecycle.

Preclinical Validation:

Proposed TruSPECT and its clinical applications successfully completed all design control testing per Spectrum Dynamics Medical's quality system and verified compliance with the relevant standards (i.e. NEMA PS3.1 - 3.20, IEC62304). The testing did not raise any new safety questions or identify any new risks. TruSPECT is designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- SW Development Lifecycle
- Testing on Unit Level (Module Verification)
- Integration Testing (System Verification)
- Performance Testing (Verification)
- Safety testing (Verification)

- Simulated Use Testing (Validation)

The testing and their results do not raise different questions of safety and effectiveness than the predicate device. Spectrum Dynamics Medical believes TruSPECT is of comparable type and substantially equivalent to the predicate device, and hence is safe and effective for its intended use. The substantial equivalence also based on software documentation for a "Moderate" level of concern device.

Clinical Evaluation

TruSPECT did not require clinical studies to support the determination of equivalence. However, the performance testing for the AI-based algorithm for iteration reconstruction process to control image attenuation have been evaluated and demonstrates algorithm's performance and uses test datasets of representative clinical exams.

The test datasets were comprised of representative clinical exams that were manually accessed by experienced NM Physicists and Physicians and were used as ground truth. The NM Physicists and Physicians also performed the algorithm evaluation. They reviewed the results and scored them using a 5-point Likert scale. The scientific methods used to evaluate the effectiveness of proposed application are acceptable and support the determination of substantial equivalence.

Substantial Equivalence

The Substantial Equivalence of the proposed device has been demonstrated by:

- Review of the proposed Indications for Use shows that they are substantially equivalent to the predicate device. Proposed Indications for Use do not create a new Intended Use.
- The device description and the comparison of device characteristics show that the proposed device has identical or equivalent technological characteristics as its predicate.
- The testing (engineering and clinical) demonstrates the efficiency of proposed device for its intended purpose.

The changes and the different technological characteristics do not raise new or different questions of safety and effectiveness. The proposed device is as safe and effective as the legally marketed predicate device as demonstrated by the:

- Software verification and validation for a Moderate level of concern, without unexpected results.

- Development under quality management system, design control activities including risk management.
- Device labeling.
- Engineering and clinical testing without unexpected results.

Conclusion:

Based on the conformance to standards, development under Spectrum Dynamics quality system, the successful verification testing, additional engineering testing, and the clinical evaluation, Spectrum Dynamics Medical believes that the ***TruSPECT*** is substantially equivalent to the predicate device, D-SPECT® Processing and Reviewing Workstation (K160120) and hence is safe and effective for its intended use.