DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2016

Spectrum Dynamics, Medical Ltd.
% Mr. Yoram Levy
QA/RA Consultant
Qsite
31 Haavoda Street
Binyamina, 30500
ISRAEL

Re: K160120
Trade/Device Name: D-SPECT® Processing and Reviewing Workstation
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, LLZ
Dated: January 13, 2016
Received: January 19, 2016

Dear Mr. Levy:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160120

Device Name
The D-SPECT® Processing and Reviewing Workstation

Indications for Use *(Describe)*
The D-SPECT® Processing and Reviewing Workstation is intended for Processing, Reporting, Archiving, Display, Communication and Analysis of emission computerized tomography data using tools for imaging and automated review and quantification of Cardiac SPECT data.
The D-SPECT® Processing and Reviewing Workstation is intended to work with Spectrum Dynamics' D-SPECT® Cardiac Scanner System or as a separate standalone post processing workstation.
The system is intended for use by the Nuclear Medicine (NM), Radiology or Electro Physiology Cardiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Dynamic, Multi-Gated) and tomographic three-dimensional scans (SPECT, Gated SPECT) acquired by gamma cameras. The system can run on a dedicated workstation or as part of Spectrum Dynamics' D-SPECT® Cardiac Scanner System. The NM data can be coupled with registered and/or fused X-Ray CT or 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. "SUMO" optional application 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 mIBG I-123 (AdreView tm Iobenguane I-123 Injection) or similar agents within the heart.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

D-SPECT® Processing and Reviewing Workstation

510(k) Number K160120

Applicant's Name: Spectrum Dynamics Medical Ltd.
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igorn@spectrum-dynamics.com

Trade Name: ***D-SPECT® Processing and Reviewing Workstation***

Common Name: Nuclear Medicine Workstation

Preparation Date: January 13, 2016

Classification: **Name**: Emission computed tomography system (Subsequent: Picture archiving and communication system)

Product Code: KPS (subsequent LLZ)

Regulation No: 21 CFR 892.1200 (subsequent 21CFR 892.2050)

Class: II

Panel: Radiology

Device Description:

D-SPECT® Processing and Reviewing Workstation 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. Visualization tools include segmentation, color 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). It 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.

D-SPECT® Processing and Reviewing Workstation is based on Windows operating system. Due to special customer requirements and the clinical focus the ***D-SPECT® Processing and Reviewing Workstation*** can be configured in the same way as the predicate device 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.

D-SPECT® Processing and Reviewing Workstation is a processing workstation primarily intended for, but not limited to

cardiac applications. The workstation can be a part of the FDA cleared D-SPECT® Cardiac Scanner System (K110507) or integrated to a separate standalone post processing station.

"SUMO" optional application 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 within the heart of mIBG I-123 (AdreView™ Iobenguane I-123 Injection) or similar agents.

Indications for use:

The ***D-SPECT® Processing and Reviewing Workstation*** is intended for Processing, Reporting, Archiving, Display, Communication and Analysis of emission computerized tomography data using tools for imaging and automated review and quantification of Cardiac SPECT data.

The ***D-SPECT® Processing and Reviewing Workstation*** is intended to work with Spectrum Dynamics' D-SPECT® Cardiac Scanner System or as a separate standalone post processing workstation.

The ***D-SPECT® Processing and Reviewing Workstation*** is intended for use by the Nuclear Medicine (NM), Radiology or Electro Physiology Cardiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Dynamic, Multi-Gated) and tomographic three-dimensional scans (SPECT, Gated SPECT) acquired by gamma cameras. The system can run on a dedicated workstation or as part of Spectrum Dynamics' D-SPECT® Cardiac Scanner System. The NM data can be coupled with registered and/or fused X-Ray CT or 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. "SUMO" optional application 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 mIBG I-123 (AdreView™ Iobenguane I-123 Injection) or similar agents within the heart.

Predicate Devices:

The proposed ***D-SPECT® Processing and Reviewing Workstation*** is substantially equivalent to the following predicate device:

Device Name	Manufacturer	510k No	Date of Clearance
D-SPECT® Cardiac Scanner System	Spectrum Dynamics	K110507	July 13, 2011

The following are reference devices:

Device Name	Manufacturer	510k No	Date of Clearance
Xeleris 3.1 Processing and Review Workstation	GE Healthcare	K130884	March 21, 2013
Emory Cardiac Toolbox 3.2	Syntermed	K130902	June 14, 2014

The D-SPECT® Cardiac Scanner System (K110507), in particular it's processing and reviewing workstation, is the primary predicate device for the subject device. It is substantially equivalent in regard to its intended use, clinical indications and fundamental technology.

The GE Healthcare's Xeleris 3.1 Processing and Review Workstation (K130884) and the Emory Cardiac Toolbox 3.2 are reference devices in regard to the additional intended use, clinical indication for use and the technical parameters of the ***D-SPECT® Processing and Reviewing Workstation***. It supports in particular the processing and reviewing workstation as a separate standalone workstation and the additional "SUMO" optional application.

Substantial Equivalence to Predicate and Reference Devices

The ***D-SPECT® Processing and Reviewing Workstation*** and its primary predicate device, the D-SPECT® Cardiac Scanner System (K110507) are

intended for the same use and have similar indications for use. Furthermore, the ***D-SPECT® Processing and Reviewing Workstation*** and its primary predicate device, the D-SPECT® Cardiac Scanner System **(**K110507), the processing station, have similar technological features.

The differences between the two devices are the separation of the processing and reviewing workstation as a separate standalone workstation and "SUMO" optional application as an additional indication.

The Xeleris 3.1 Processing and Review Workstation (K130884) and the Emory Cardiac Toolbox 3.2 **(**K130902) are reference devices**,** which support the additional intended use of ***D-SPECT® Processing and Reviewing Workstation*** as a separate standalone workstation for post image processing.

The Xeleris 3.1 Processing and Review Workstation (K130884) and the Emory Cardiac Toolbox 3.2 **(**K130902) are reference devices which support the additional "SUMO" optional application.

Any minor differences in the design do not raise any new questions of safety and effectiveness issues, as verified by performance testing.

Results of tests and validations, performed with the proposed ***D-SPECT® Processing and Reviewing Workstation*** demonstrates that it is as safe and effective as its primary predicate device, without raising any new safety and/or effectiveness concerns.

Therefore, the D-SPECT® Processing and Reviewing Workstation is substantially equivalent to its predicate devices.

Performance Standards:

D-SPECT® Processing and Reviewing Workstation complies with:

- ***ISO 62304*** Medical device software- Software life cycle processes
- ***ISO 14971*** Medical Devices- Application of risk management to medical devices
- ***ISO 15223-1*** Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1

- **IEC 60601-l-4** General requirements for safety – Collateral Standard: Programmable electrical medical systems

- **IEEE Std 3333.2.1-2015** IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling

- **DICOM PS 3.1-3.18** standard Digital Imaging and Communications in Medicine (DICOM) Standard

Performance Bench Tests

Bench testing demonstrated that the ***D-SPECT® Processing and Reviewing Workstation*** is as safe and effective as the cleared predicate devices.

The performance tests were done in addition to the successful completion of verification and validation testing as required by Spectrum Dynamics Medical quality system (per 21CFR 820 Quality System Regulation and ISO 13485 standard). Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or identify any new risks.

To demonstrate and validate the safety, effectiveness and clinical use of the modified D-SPECT® Processing and Reviewing Workstation using SUMO application, Spectrum Dynamics performed a number of validation and verification tests including overall performance study using a simulated phantom and a dataset of subjects in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff, Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions.

The performance tests indicate that the D-SPECT® Processing and Reviewing Workstation meets the specification requirements.

Summary of Pre-Clinical and clinical study

D-SPECT® Processing and Reviewing Workstation is a Processing Workstation primarily intended for, but not limited to cardiac applications. The system is intended for use by the Nuclear Medicine (NM), Radiology or Electro Physiology Cardiology practitioners, and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Dynamic, Multi-Gated) and tomographic three-dimensional scans (SPECT, Gated SPECT) acquired by gamma cameras.

The safety and efficacy of the ***D-SPECT® Cardiac Scanner System*** device has been well established in scientific research due to the comprehensive clinical studies, scientific research and published literature of SPECT devices using the same technology and with its predicate devices, Spectrum Dynamics Ltd. believes that animal and clinical studies are not required to determine the safety and efficacy of the device.