



Food and Drug Administration
10903 New Hampshire Avenue
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Spectrum Dynamics Medical Ltd
% Mr. Igor Naroditsky
Director QA/RA
22 Bareket Street
Caesarea, 3088900
ISRAEL

November 4, 2016

Re: K161740
Trade/Device Name: D-SPECT[®] Cardiac Scanner System
D-SPECT[®] L Cardiac Scanner System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 1, 2016
Received: August 11, 2016

Dear Mr. 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. 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, light blue watermark of the FDA logo.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161740

Device Name

D-SPECT® Cardiac Scanner

D-SPECT® L Cardiac Scanner

Indications for Use (Describe)

The D-SPECT® Cardiac Scanner is an emission computed tomography system intended for detection of radioisotope tracer uptake in the patient's body and produce cross-sectional images through computer reconstruction of the data. The system uses a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated and Dynamic) and tomographic mode (Static, Multi-gated and Dynamic). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include gating by physiological signals, real-time body movement control, and low count rate (low dose) acquisition without loss of image quality.

The D-SPECT® Cardiac Scanner may consist analysis and display equipment contain data and image processing software to produce images in a variety of trans-axial and reformatted planes. To perform analysis and uptake quantitation and to apply the appropriate filters. The system utilizes combined images for attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration and fusion).

The D-SPECT® Cardiac Scanner is intended for use by the appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of (but not limited) cardiac or individual organs diseases. The system output can be used for planning, guiding, and monitoring therapy.

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® Cardiac Scanner System

510(k) Number K161740

Identification of the Submitter

Submitter: Igor Naroditsky, Director QA/RA
Spectrum Dynamics Medical Ltd.
22 Bareket St. Caesarea, Israel 3088900.

Telephone Number: + (972) 73-737-4500,
Fax Number: + (972) 73-737-4501

Name / Address of Manufacturer: Spectrum Dynamics Medical Ltd.
22 Bareket St. Caesarea, Israel 3088900.

Date of Submission: 30 May 2016

Identification of the product

Device Proprietary Names: **D-SPECT® Cardiac Scanner System**
D-SPECT® L Cardiac Scanner System

Common/Classification Names: Emission computed tomography system

Class: II

Product Code: KPS

Classification Panel: Radiology

Regulation No: 21 CFR 892.1200

Marketed Devices to which Equivalence is claimed

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
D-SPECT™ Cardiac Scanner	Spectrum Dynamics Medical Ltd.	K110507

Reference Devices:

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
D-SPECT® Processing and Reviewing Workstation	Spectrum Dynamics Medical Ltd.	K160120
Discovery NM/CT 670 CZT	GE Healthcare	K153402

Device Description:

Spectrum Dynamics D-SPECT® Cardiac Scanner System is a single photon emission computing tomography system intended for detection of radioisotope tracer uptake in the body and produce cross-sectional images through computer reconstruction of the data.

The device uses a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. System's scanning modes include planar mode (Static, Multi-Gated and Dynamic) and tomographic mode (Static, Multi-Gated and Dynamic). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include gating by physiological signals, real-time body movement control. The device may proceed a low count rate (low dose) acquisition without loss of image quality. The device may utilize variate modalities to create attenuation corrected images along with functional and anatomical mapping imaging (localization, registration and fusion).

The device is a high performance and compact Single Photon Emission Computed Tomography system intended for imaging of the breast and additional small organs in order to aid in the evaluation of lesions.

The system detectors support radionuclides within the energy range of 40 -170 Kev.

D-SPECT® Cardiac Scanner System comprising detector head, gantry, patient supports, uninterruptible power supply (UPS), image display and processing equipment, gating and real-time body movement control tools, interconnecting cables and related appurtenances.

The device is available in two models, D-SPECT with nine detectors configuration and the D-SPECT L with six detectors configuration.

D-SPECT® Cardiac Scanner System consist integrated signal analysis and display equipment or may use an FDA cleared D-SPECT® Processing and Reviewing Workstation (K160120) for image processing.

D-SPECT Cardiac Scanner System is intended for use by the appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of (but not limited) cardiac diseases. The system output can be used for planning, guiding, and monitoring therapy.

Intended Use Statement:

The D-SPECT Cardiac Scanner System is an emission computed tomography system intended for detection of radioisotope tracer uptake in the patient's body and produce cross-sectional images through computer reconstruction of the data. The system uses a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated and Dynamic) and tomographic mode (Static, Multi-gated and Dynamic). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include gating by physiological signals, real-time body movement control, and low count rate (low dose) acquisition without loss of image quality.

The D-SPECT Cardiac Scanner System may consist analysis and display equipment contain data and image processing software to produce images in a variety of trans-axial and reformatted planes. To perform analysis and uptake quantitation and to apply the appropriate filters. The system utilizes combined images for attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration and fusion).

The D-SPECT Cardiac Scanner System is intended for use by the appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of (but not limited) cardiac or individual organs diseases. The system output can be used for planning, guiding, and monitoring therapy.

Predicate Devices:

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
D-SPECT tm Cardiac Scanner	Spectrum Dynamics Medical Ltd.	K110507

Reference Devices:

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
D-SPECT® Processing and Reviewing Workstation	Spectrum Dynamics Medical Ltd.	K160120
Discovery NM/CT 670 CZT	GE Healthcare	K153402

Substantial Equivalence to Predicate Devices

D-SPECT scanner is a modification of the D-SPECT Cardiac Scanner (K110507) that reorganizes the system's indications for use and introduces an additional device model.

D-SPECT® Scanner and its predicate, the Spectrum Dynamics D-SPECT Cardiac Scanner (K110507) have the similar indication for use and both utilize same fundamental technology. Discovery NM/CT 670 CZT (K153402), in particular its NM part, is supporting modified intended use. D-SPECT® Processing and Reviewing Workstation (K160120) supports image post processing modalities.

Both devices the modified D-SPECT Cardiac Scanner System and its predicate D-SPECT Cardiac Scanner are intended for use by the appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of (but not limited) cardiac or individual organs diseases. The system output can be used for planning, guiding, and monitoring therapy. The intended use of the subject device has been reorganized and extended to support and clarify a well-established imaging modalities.

Discovery NM/CT 670 CZT (K153402), especially its NM part, uses to support intended use reorganization.

Technology characteristic

D-SPECT® Cardiac Scanner System based on the commercially available D-SPECT™ Cardiac Scanner (K110507). The modified D-SPECT Cardiac Scanner System hardware based on the same fundamental technology and utilize same CZT detectors, collimators and image reconstruction tools. The device efficacy and safety as well as the performance specifications remain the same.

Performance testing

D-SPECT® Cardiac Scanner System is designed in accordance with the EN 60601 series of standards, including all relevant collateral standards, i.e. IEC 60601-1, 1-2, etc. Device

performance validation testing conducted according to NEMA NU-1:2012. All testing results are met the predetermined acceptance values.