April 25, 2018

Spectrum Dynamics Medical Ltd.
% Mr. Igor Naroditsky
Director QA/RA
22 Bareket St. North Industrial Park
Caesarea 3088900
ISRAEL

Re: K180514
Trade/Device Name: VERITON™ NM
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 27, 2018
Received: February 27, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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)*
K180514

Device Name
VERITON™ NM

Indications for Use *(Describe)*
VERITON™ NM is a Nuclear Medicine (NM) imaging system, intended to perform general nuclear medicine imaging procedures for the detection of radioisotope tracer uptake in a patient's body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality.
Scanning modes include whole body and tomographic (static, dynamic and multi-gated) mode, while acquisition types include single and multi-isotope single-photon imaging. Imaging-enhancement features include gating by way of physiological signals and real-time automatic body contouring.

The VERITON™ NM system is a medical device intended for use by appropriately-trained healthcare professionals to aid in the detection, localization and diagnosis of diseases and organ function, for the evaluation of diseases, trauma, abnormalities and disorders. System output can be used by a physician for planning, guiding, and monitoring therapy.

SPECT: To detect or image the distribution of radionuclides in the body or organ, using the following techniques: whole body imaging and tomographic imaging.

Software: System application software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, CT and other imaging modalities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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7. PREMARKET NOTIFICATION 510(K) SUMMARY

The Company's 510(k) summary as required by 21 CFR Part 807.87(h) and 21 CFR Part 807.92(c) is provided on the following pages.

510(k) SUMMARY OF SAFETY AND EFFECTIVNESS

510(k) Number K180514

Date of submission:	February 28, 2018
Submitter:	Spectrum Dynamics Medical Ltd. 22 Bareket St. North Industrial Park Caesarea, Israel 3088900.
Submitter Contact:	Mr. Igor Naroditsky Director QA/RA Tel: + (972) 73-737-4548 Fax: + (972) 73-737-4502 Email: igorn@spectrum-dynamics.com
Device Trade Name:	VERITON™ NM
Common Name/Classification:	Emission computed tomography system/Single Photon Emission Computed Tomography (SPECT)
Class:	II
Product Code:	90 KPS
Classification Panel:	Radiology
Regulation No:	Emission Computed Tomography per 21 CFR 892.1200

Marketed Devices:

VERITON™ NM is a modification to the D-SPECT® (K160740) that extends the system's intended use. The detectors are built of the exact same CZT modules that are used in D-SPECT® (K16740). The differences are the construction of the gantry and number of detectors used as well as to the patient support. The new gantry has an inner bore of 800mm diameter and includes a base, stator and rotor. It has 12 detector units within a ring configuration.

Predicate device:

Spectrum Dynamics Medical's D-SPECT® Scanner (K161740)

Referenced device:

Siemens Symbia 6.5 system (K162337).

Device Description:

Spectrum Dynamics VERITON™ NM system is a single photon emission computing tomography system (SPECT) intended for detection of radioisotope tracer uptake in the body and to 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 system may utilize various modalities to create attenuation corrected images along with functional and anatomical mapping imaging (localization, registration and fusion).

The VERITON™ NM system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include data and image processing to produce images in a variety of trans-axial and reformatted planes. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation. The system may be used for patients of all ages.

Intended Use:

VERITON™ NM is a Nuclear Medicine (NM) imaging system, intended to perform general nuclear medicine imaging procedures for the detection of radioisotope tracer uptake in a patient's body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality.

Scanning modes include whole body and tomographic (static, dynamic and multi-gated) mode, while acquisition types include single and multi-isotope single-photon imaging. Imaging-enhancement features include gating by way of physiological signals and real-time automatic body contouring.

The VERITON™ NM system is a medical device intended for use by appropriately-trained healthcare professionals to aid in the detection, localization and diagnosis of diseases and organ function, for the evaluation of diseases, trauma, abnormalities and disorders. System output can be used by a physician for planning, guiding, and monitoring therapy.

SPECT: To detect or image the distribution of radionuclides in the body or organ, using the following techniques: whole body imaging and tomographic imaging.

Software: System application software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, CT and other imaging modalities.

Technological characteristic:

VERITON™ NM employs the same fundamental scientific technology as the predicate device Spectrum Dynamics D-SPECT® Scanner (K161740). The detectors and general performance specifications have not changed between the commercially available D-SPECT® Scanner (K161740) and proposed VERITON™ NM system.

Determination of substantial equivalence:

Performance testing

VERITON™ NM system has been 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 have met the predetermined acceptance values. The additional non-clinical performance evaluation testing used a variety of test methods and phantoms appropriate for the performance metric/claim that was to be tested and evaluated. Mathematical and physics analysis were performed to demonstrate that each performance metric/claim was successfully verified and substantiated. The areas additionally evaluated for the non-clinical testing included energy resolution, count rate linearity, uniformity, system resolution and lesion detectability.

Summary of Non-Clinical Testing:

The device has successfully completed all design control testing per our quality system. No new hazards were identified and no unexpected test results were obtained. The VERITON™ NM system was 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
- Design Reviews
- Software Development Lifecycle

- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Spectrum Dynamics believes VERITON™ NM system is substantially equivalent to D-SPECT® Scanner (K161740). The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

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 VERITON™ NM is substantially equivalent to the predicate device D-SPECT® Scanner (K161740) and hence is safe and effective for its intended use.