Spectrum Dynamics Medical Ltd
℅ Igor Naroditsky
VP QA/RA
22 Bareket St.
North Industrial Park. Caesarea 3079837
ISRAEL

July 12, 2019

Re: K190457
Trade/Device Name: VERITON™ CT whole body SPECT/CT system
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: May 26, 2019
Received: June 11, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190457

Device Name

VERITON™ CT whole body SPECT/CT system

Indications for Use *(Describe)*

The Spectrum Dynamics Medical's VERITON™ CT is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and trauma. The system output can be used for planning, guiding, and monitoring therapy.

SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques; whole body and tomographic imaging.

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data (anatomy) from either the same axial plane taken at different angles or spiral planes take at different angles. The CT part is indicated for pediatric and adult patients.

SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

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 OF SAFETY AND EFFECTIVNESS

510(k) Number: K190457

Date of submission:	Feb 20, 2019
Submitter:	Spectrum Dynamics Medical Ltd. 22 Bareket St. North Industrial Park Caesarea, Israel 3079837.
Submitter Contact:	Mr. Igor Naroditsky, VP QA/RA Tel: + (972) 73-737-4548 Fax: + (972) 73-737-4502 Email: igorn@spectrum-dynamics.com
Device Trade Name:	VERITON® CT
Common Name/Classification:	Single Photon Emission Computed Tomography (SPECT)/Computed Tomography (CT) system
Class:	II
Product Code:	KPS and JAK
Classification Panel:	Radiology
Regulation No:	Emission Computed Tomography per 21 CFR 892.1200

Marketed Devices:

The Spectrum Dynamics VERITON® CT 16 system is a modification to the VERITON® CT 64 system (K182484), the difference between the two models in the CT configuration used, 16 slices in compare to 64 in predicate. All other items in the system are the same as in the VERITON® CT 64 (K182484) and have the same functionality and performance.

Predicate device:

Spectrum Dynamics Medical's VERITON® CT 64 (K182484)

Referenced device:

Analogic Corporation CT1685 (K182147) Computed Tomography (CT) Scanner to support proposed 16 slice CT.

Device Description:

VERITON® CT consists of Single Photon Emission Computed Tomography (SPECT) scanners and integrated X-Ray Computed Tomography (CT). The SPECT subsystem images and measures the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and integrates the CT's anatomical details for precise reference of the location of the metabolic activity. The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The system can be used as an integrated SPECT and CT modality while also enabling independent functionality of SPECT and CT as stand- alone diagnostic imaging devices.

Intended Use:

The Spectrum Dynamics Medical's VERITON® CT is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and trauma. The system output can be used for planning, guiding, and monitoring therapy.

SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques; whole body and tomographic imaging.

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SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

Technological characteristic:

Spectrum Dynamics' VERITON® CT 16 employs the same fundamental scientific technology as it's predicate device VERITON® CT 64 (K182484). The CZT detectors, system architecture and SPECT performance specifications have not changed between the commercially available VERITON® CT 64 (K182484) and proposed VERITON® CT 16 system.

The CT Gantry is similar to the one used by Analogic Corporation CT1685 (K182147) Computed Tomography (CT) Scanner.

Determination of substantial equivalence:

Performance testing

Verification & Validation includes testing for Biocompatibility, Software, Electrical Safety / EMC, Consensus Standard testing applicable for SPECT/CT scanners, mitigation measures set forth in device specific regulations (21CFR §1020.30, §1020.33), and usability. These tests were conducted to characterize the performance of the proposed device functionality against that of the predicate device. The supplementary non-clinical performance evaluations 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 included energy resolution, count rate linearity, uniformity, system resolution and lesion detectability. All testing has met the acceptance criteria for the proposed device.

Summary of Non-Clinical Testing:

The device has successfully completed all design control testing as per our quality system. No new hazards were identified, and no unexpected test results were obtained. The VERITON® CT 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 that the VERITON® CT 16 system is substantially equivalent to the VERITON® CT 64 system (K182484). The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Clinical Testing:

Sample clinical images of the SPECT, CT and SPECT/CT modalities were evaluated by a board-certified radiologist to confirm that the images were of diagnostic quality.

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® CT 16 is substantially equivalent to the predicate device, VERITON® CT 64 system (K182484) and hence is safe and effective for its intended use.