



Food and Drug Administration
10903 New Hampshire Avenue
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Arineta Ltd.
% Mr. Ehud Dafni
CEO
15 Halamish Street
Caesarea, 3088900
ISRAEL

August 10, 2016

Re: K161066
Trade/Device Name: SpotLight CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 11, 2016
Received: July 14, 2016

Dear Mr. Dafni:

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

Indications for Use

510(k) Number (if known)

K161066

Device Name

SpotLight CT

Indications for Use (Describe)

The SpotLight CT Computed Tomography X-ray is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission projection data taken at different angles. The system has the capability to image whole organs, including the heart, in a single rotation. The system may acquire data using Axial, Cine and Cardiac CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes.

The system is indicated for X-ray Computed Tomography imaging of organs that fit in a 25cm field of view, including cardiac and vascular CT imaging. The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.

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

Arineta Ltd.'s SpotLight CT

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92

Date prepared: April 12, 2016

Submitted by: Arineta Ltd.
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PRODUCT IDENTIFICATION

Device Trade Name: SpotLight CT

Common/Usual Name: Computed Tomography X-ray System

Classification Name: Computed Tomography X-ray System
(21CFR 892.1750)

Product Code: 90-JAK

Predicate Device: GE Healthcare Revolution CT K133705

References Devices: Siemens Somatom Definition Flash (K121072),
Elscint Excel CT Twin (K915738), Philips Mx8000
(K010817), Toshiba Equilion One Vision (K142465),
Philips Brilliance iCT (K131773)

INTENDED USE

The Spotlight CT Computed Tomography X-Ray system is intended for head, body, cardiac and vascular X-ray Computed Tomography applications.

INDICATIONS FOR USE

The SpotLight CT Computed Tomography X-ray is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission projection data taken at different angles. The system has the capability to image whole organs,

including the heart, in a single rotation. The system may acquire data using Axial, Cine and Cardiac scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

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DEVICE DESCRIPTION

The SpotLight CT is a third generation rotate-rotate CT scanner, designed and built based on technologies and principles of operation of the predicate device and other legally marketed CT scanners. The SpotLight CT is a multi-slice (192 detector rows), dual tube CT scanner consisting of a gantry, patient table, operator console, power distribution unit (PDU) and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software and software for operator interface and image handling.

Technological Characteristics / Principles of Operation

The system generates images through computed reconstruction of data acquired at different view angles of the rotating gantry, while irradiating the scanned subject by two alternating X-ray sources. The gantry rotates at up to 0.24 seconds per rotation and can acquire up to 240 slices of image data in a single axial scan with a maximum total coverage of 140 mm in the z direction. While the system covers field of view (FOV) of 450 mm, the radiation outside 250 mm (or 160 mm) FOV is attenuated, providing diagnostic image quality up to 250 mm FOV. The system can be operated in axial (partial or full scan), cine, cardiac and ECG gated modes.

The SpotLight CT is a powerful, volumetric, high resolution CT that is designed to provide whole organ coverage, high image quality and uncompromised dose performance with the following features:

- 140 mm detector coverage;
- 120 msec temporal resolution (at 0.24 second rotation speed);
- 0.31 mm spatial resolution;
- 250 mm diagnostic FOV;
- Reduced cone beam artifacts.

The SpotLight CT features two “Gemini” X-ray tubes to provide two X-ray sources displaced in the z axis (parallel to rotation axis). The sources are alternating using electrostatic grid control, such that the scanned subject is irradiated alternatively by two

overlapping cone X-ray beams while the gantry rotates and attenuation data is acquired by a single array detector. Image reconstruction is accomplished by a Stereo CT reconstruction algorithm based on common algorithms used in single source scanners that are modified to combine the data acquired from the two sources.

The detector array comprises of three regions, center part covering FOV 250 mm with high pitch detector array and two peripheral parts with lower pitch detector arrays. The data acquired in the peripheral parts is useful for patient positioning (scout scan) and for elimination of truncation artifacts from the images. The detector array features anti-scatter collimator (post patient) to reduce scatter artifacts, ensure CT number uniformity and reduce beam hardening artifacts.

The gantry features a short source to axis distance (SAD) of 450 mm, resulting in higher usable X-ray flux at a given source voltage and current as compared to scanners with longer SAD.

DEVICE TESTING

The SpotLight CT has completed testing and is in compliance with AAMI/ES 60601-1, IEC 60601-1 Ed. 3 and its associated collateral standards and particular standards, 21CFR Subchapter J and NEMA XR-25, XR-28 and XR-29.

Testing included:

- Testing on unit level;
- Integration testing (system verification);
- Performance testing (verification);
- Safety testing (verification);
- Simulated use testing (validation);
- Animal testing (validation);
- Clinical testing (validation).

The device was developed under a rigorous quality system and has successfully completed design control activities, including risk management, verification and validation.

Non-clinical Performance Testing

The performance evaluation used a variety of test methods, phantoms and scan conditions. Various mathematical, physics and statistical analyses were performed to demonstrate that performance specifications are met. The tests evaluated image quality, temporal resolution and dose performance. Image quality evaluation included evaluation of artifacts, spatial resolution, low contrast detectability, noise, and uniformity and CT number accuracy.

Animal Testing

The scanner was tested on a porcine model with and without contrast injection, with and without ECG gating at different heart rates. The trial included three cardiac CTA studies under different conditions, abdomen (renal) scan and neck (carotids) CTA. The images were evaluated for diagnostic quality with positive results.

Clinical Testing

Clinical data were collected on 38 subjects at one site with the approval of appropriate ethics committee and in accordance with applicable regulatory requirements as well as Arineta quality system procedures. The study protocol was designed to test the scanner across different patient populations, clinical scenarios and scan techniques.

Image data sets included:

- Cardiac – Coronary CTA, cardiac function, calcium burden, preparation for TAVI
- Body – Abdomen (at a limited field of view), spine
- Head – brain, inner ear

The images were evaluated and rated by four US certified readers who are qualified radiologists or cardiologists for clinical diagnostic value and image quality.

The results of this clinical testing demonstrate the diagnostic image quality performance of the SpotLight CT, as well as the safety and efficacy of the device.

SUBSTANTIAL EQUIVALENCE

Based on the extensive testing as described above, the SpotLight CT is as safe and effective as the Revolution CT. The SpotLight CT has the same intended uses and similar indications, technological characteristics, energy type and principles of operation as its predicate device. The technological differences between the SpotLight CT and its predicate devices raise no new issues of safety or effectiveness. Thus, the SpotLight CT is substantially equivalent.

CONCLUSION

Based on the conformance to standards, as well as the bench and clinical testing provided, Arineta Ltd. believes that the SpotLight CT is substantially equivalent to the predicate device, GEHC Revolution CT (K133705).