December 2, 2022

Arineta Ltd.
℅ Tanya Shalem
Director QA&RA
15 Halamish Street
Caesarea, 3088900
ISRAEL

Re: K213465
Trade/Device Name: SpotLight Duo
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: November 4, 2022
Received: November 4, 2022

Dear Tanya Shalem:

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,

Lu Jiang
2022.12.02
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Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K213465

Device Name
SpotLight Duo

Indications for Use *(Describe)*

The SpotLight Duo 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.

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 the scan 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K213465

510(k) SUMMARY

Arineta's SpotLight Duo

Submitter

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Contact Person: Tanya Shalem, VP of QA&RA

Date Prepared: August 12, 2022

Name of Device: SpotLight Duo

Common or Usual Name: Computed Tomography X-ray System

Regulation Medical Specialty: Radiology

Regulation Number: 892.1750

Regulatory Class: Class II

Product Code: JAK

Predicate Devices

Device Name	Manufacturer	510(k) Number
SpotLight CT	Arineta Ltd.	K161066
Revolution CT	GE Healthcare LLC	K133705

Device Description

The SpotLight Duo 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. As in other CT scanners, a scanned subject is irradiated by X rays and a detector array measures attenuation data of X rays that have been attenuated by the subject from multiple view angles. This is achieved by rotation of the radiation source and the detector about the subject while acquiring the attenuation data. A computer is used to reconstruct cross sectional images of the subject from the attenuation data.

The primary predicate, SpotLight CT (K161066), reconstructs high resolution images up to Field of View (FOV) 250mm. Scout images used for patient positioning and scan planning are reconstructed and displayed at a wide FOV larger than 250mm.

The primary changes in the modified SpotLight Duo device include two optional configurations:

1. Wide FOV – reconstructs high resolution images up to 450mm FOV. 10 HR detector modules replace LR detector modules (as in the primary predicate) on one wing of the detector. Therefore, there are 33 HR modules instead of 23 HR modules. Although the HR part of the detector is asymmetric, the device is capable of imaging the entire FOV of 450mm at high resolution when acquiring data for 360º of rotation. The data from the LR wing is still used to avoid truncation artifacts.
2. Extended FOV – reconstructs high resolution images up to 250mm FOV and 250-450mm low resolution FOV with no change to the detector.

- Both configurations include software adaptation to 450mm FOV. The software is modified to support data acquisition with the modified detector, reconstruction at larger FOV, scan modes and protocols according to configuration.
- There is an additional minor adaptation to collimator to support wide FOV collimation (250mm/450mm).

Intended Use

The SpotLight Duo is intended to be used for body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use

The SpotLight Duo 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.
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 the scan 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.

Technological Characteristics

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 560 overlapping 0.5mm slices of image data in a single axial scan with a maximum total coverage of 140mm in the z direction. While the basic scanner (SpotLight CT) covers a field of view (FOV) of 450mm, the radiation outside

250mm (or 160mm) FOV is attenuated, providing diagnostic image quality up to 250mm FOV. With the Extended and Wide Field of View configurations, the system is adapted to provide standard resolution (STD) or high resolution (HR) diagnostic images at FOV 450mm. The system can be operated in axial (partial or full scan), cine, cardiac and ECG gated modes.

The SpotLight Duo features two MCS-2093 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.

A table comparing the key features of the subject and predicate devices is provided below.

	Proposed device – SpotLight Duo	**Primary predicate - SpotLight CT (K161066)**	**Secondary predicate – Revolution CT (K133705)**	**Discussion**
Detector technology and geometry	Fast scintillator array coupled to photodiode array. 33 (WFOV) or 23 (EFOV) configurable high resolution (HR) modules comprising 192 detector rows X pitch 0.5mm (Z direction, measured at scanner center). 10(WFOV) or 20 (EFOV) configurable low resolution (LR). EFOV includes 10 modules on each wing while WFOV includes 10 modules on one wing. comprising 48 detector rows X pitch 2.0mm Analog to digital conversion per channel on the detection module. 1D antiscatter collimator.	Fast scintillator array coupled to photodiode array. 23 high resolution (HR) modules comprising 192 detector rows X pitch 0.5mm (Z direction, measured at scanner center). 20 low resolution (LR) modules (10 on each wing) comprising 48 detector rows X pitch 2.0mm Analog to digital conversion per channel on the detection module. 1D antiscatter collimator.	Fast scintillator (garnet) array coupled to photodiode array. 256 detector rows X pitch 0.625mm (Z direction, measured at scanner center). Analog to digital conversion per channel on the detection module. 2D antiscatter collimator. All detectors are from the same type (full FOV).	Same technology and sub-assemblies as the primary predicate. The proposed device adds optional configurations with wider field of view (FOV) than the primary predicate, as available in the secondary predicate.
Data transmission from rotor	Contactless transmission (capacitive coupling). Rate up to 6.25 GBit/sec	Contactless transmission (capacitive coupling). Rate up to 6.25 GBit/sec	Contactless transmission (capacitive coupling). Rate up to 40 GBit/sec	Same
Power and control transmission to rotor	Contact less transmission	Brush contact slipring	Contact less transmission	Same as secondary predicate
Rotation drive	Direct drive DC motor	DC motor and belt	Direct drive DC motor	Same as secondary predicate
X Ray source	2 x MCS 2093 X ray tubes by Varex Imaging Corp.	2 x MCS 2093 X ray tubes by Varex Imaging Corp.	Perfomex HDwX ray tube by GEHC	Same as primary predicate

	Proposed device – SpotLight Duo	Primary predicate - SpotLight CT (K161066)	Secondary predicate – Revolution CT (K133705)	Discussion
	Single ended grounded rotating anode Anode angle 13 degrees 1.0 MHU anode heat capacity Grid controlled focal spot modulation in X direction Small and large focal spots Max kVp: 140 kV Max power: 72 KW	Single ended grounded rotating anode Anode angle 13 degrees 1.0 MHU anode heat capacity Grid controlled focal spot modulation in X direction Small and large focal spots Max kVp: 140 kV Max power: 72 KW	Single ended grounded rotating anode Anode angle 10.5 degrees 5.5 MHU anode heat capacity Grid controlled focal spot modulation in X direction Small, large and extra-large focal spots Max kVp: 140 kV Max power: 103 KW	
Patient table	Motorized vertical and horizontal motion Optional lateral motion Cantilever carbon fiber patient cradle.	Motorized vertical and horizontal motion Optional lateral motion Cantilever carbon fiber patient cradle.	Motorized vertical and horizontal motion Optional lateral motion. Cantilever carbon fiber patient cradle.	Same
Image reconstruction hardware	Multicore PC and GPU	Multicore PC and GPU	Multicore PC and GPU	Same
Image reconstruction algorithm	Modified FDK cone beam algorithm adapted for dual tubes geometry. Adaptive filter to reduce directional noise in low level raw data (MBAF) Iterative reconstruction algorithm (ASIR-CV) For WFOV configuration, adapted to reconstruct high resolution images according to detector configuration, lower resolution images outside FOV covered by high resolution detectors. For extended FOV configuration, adapted to reconstruct high resolution images up to FOV250mm, lower resolution images outside FOV250mm.	Modified FDK cone beam algorithm adapted for dual tubes geometry. Adaptive filter to reduce directional noise in low level raw data (MBAF) Iterative reconstruction algorithm (ASIR-CV) Adapted to reconstruct high resolution images up to FOV250mm, lower resolution images outside FOV250mm	GE proprietary VHD cone beam algorithm. Iterative reconstruction algorithm (ASiR-V).	Same algorithm as primary predicate. The primary predicate reconstructs high resolution images up to FOV250mm. The proposed device reconstructs high resolution images according to optional configuration, up to FOV450mm, as the secondary predicate.

	Proposed device – SpotLight Duo	Primary predicate - SpotLight CT (K161066)	Secondary predicate – Revolution CT (K133705)	Discussion
Construction Materials	Metal parts (mostly steel and aluminum) Lead and tungsten for X-ray shielding PCB, electronic components and electronic cables components Table top made of carbon fiber reinforced resin Covers made pf molded polymers and reinforced resins Oil in X-ray tubes cooling systems Detector scintillators made of $CdWO_4$ and Gadolinium Oxysulfide (GOS) used in other legally marketed CT scanners	Metal parts (mostly steel and aluminum) Lead and tungsten for X-ray shielding PCB, electronic components and electronic cables components Table top made of carbon fiber reinforced resin Covers made pf molded polymers and reinforced resins Oil in X-ray tubes cooling systems Detector scintillators made of $CdWO_4$ and Gadolinium Oxysulfide (GOS) used in other legally marketed CT scanners	Metal parts (mostly steel and aluminum) Lead and tungsten for X-ray shielding PCB, electronic components and electronic cables components Table top made of carbon fiber reinforced resin Covers made pf molded polymers and reinforced resins Oil in X-ray tube and detector cooling systems Detector scintillators made of GE proprietary garnet scintillator	Same
Energy sources	Wall supply 380 to 480 V 3 phase Max power demand 115 kVA Max X ray power (total for two tubes) 72kW Laser alignment lights: gantry bore external lasers. <0.1mW per laser beam Three lead ECG trigger module, powered by medical grade power supply through the system PDU	Wall supply 380 to 480 V 3 phase Max power demand 115 kVA Max X ray power (total for two tubes) 72kW Laser alignment lights: gantry bore external lasers. <0.1mW per laser beam Three lead ECG trigger module, powered by medical grade power supply through the system PDU	Wall supply 380 to 480 V 3 phase Max power demand 150 kVA Max X ray power 103kW Laser alignment lights: gantry bore internal and external lasers. <0.1mW per laser beam Four lead ECG trigger module	Same
Software	The SpotLight is provided with software in three domains: • Console software • Image reconstruction software • Embedded software The software is modified to support data acquisition with the modified detector, reconstruction at larger FOV, scan modes and protocols according to configuration.	The SpotLight is provided with software in three domains: • Console software • Image reconstruction software • Embedded software	The Revolution CT is provided with software serving same functionalities as the proposed device and complying with same standards.	Substantially the same

	Proposed device – SpotLight Duo	Primary predicate - SpotLight CT (K161066)	Secondary predicate – Revolution CT (K133705)	Discussion
Max Rotation speed	250 RPM (0.24 sec per rotation)	250 RPM (0.24 sec per rotation)	214 RPM (0.28 sec per rotation) Gantry supports 300 RPM (0.2 sec per rotation)	The differences in performance of the proposed device and primary predicate are optional higher image resolution at FOV larger than 250mm in lieu of FOV160mm collimation. The proposed device and the secondary predicate offer a larger HR FOV.
Min scan time	0.16 sec (partial), 0.24 sec (full scan) – FOV up to 250mm 0.24 sec (full scan) – HR imaging at FOV above 250mm for asymmetric detector	0.16 sec (partial), 0.24 sec (full scan)	0.28 sec (full scan)	
Max axial coverage in a single axial scan	140mm (280 slices x 0.5mm pitch)	140mm (280 slices x 0.5mm pitch)	160mm (256 slices x 0.625mm pitch)	
Field of View (FOV)	High resolution images at configurable FOV between 250mm and 450mm Lower resolution in the FOV between HR coverage and 450mm	250mm or 160mm at high resolution Optional, up to 450mm with lower resolution outside FOV 250mm	Up to 500mm	
Max spatial resolution	17.5 lp/cm cutoff at center 10.0 lp/cm cutoff at radius above 125mm (outside FOV 250mm) covered by HR detectors 7.0 lp/cm cutoff at radius above 125mm (outside FOV 250mm) covered by LR detectors	17.5 lp/cm cutoff at center 7.0 lp/cm cutoff at radius above 125mm (outside FOV 250mm)	21.4 lp/cm (cutoff)	
Bore size	60 cm	60 cm	80 cm	Same as primary predicate
Max Patient weight	227 Kg (500 lbs)	227 Kg (500 lbs)	227 Kg (500 lbs)	Same as primary predicate
Add on parts and accessories	Built in trigger ECG (Ivy Biomedical CTM300 K083854) Operator console table and/or chair Integrated Injector (Bayer Connect.CT K182273, K173773) Various table accessories Bar code reader USB data storage device	Built in trigger ECG (Ivy Biomedical CTM300 K083854) Operator console table and/or chair Integrated Injector (Bayer Connect.CT K182273, K173773) Various table accessories Bar code reader USB data storage device	Operator console table Enhanced Injector Class IV NG2000 Table slickers Bar code reader Uninterruptible Power Supply	Same as primary predicate

	Proposed device – SpotLight Duo	Primary predicate - SpotLight CT (K161066)	Secondary predicate – Revolution CT (K133705)	Discussion
	Console Uninterruptible Power Supply Partial System Uninterruptible Power Supply A1 Disconnect panel 20cm Water phantom QA phantom Seismic kit Mobile kit	Console Uninterruptible Power Supply Partial System Uninterruptible Power Supply A1 Disconnect panel 20cm Water phantom QA phantom Seismic kit Mobile kit		

Testing of the modifications to the primary predicate, SpotLight CT (K161066), as well as the SpotLight Duo as a whole included:

- Testing on unit level
- Integration testing
- Performance testing
- Safety testing

Non-Clinical Performance Testing

The electromagnetic compatibility of the SpotLight Duo was tested and was found to be in compliance with the requirements of the following standards:

- IEC 60601-1:2005+AMD1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test
- IEC 60601-1-3:2008+AMD1:2013 - Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-44:2009/AMD1:2012 - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

SpotLight Duo was tested 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.

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

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 and dose performance. Image quality evaluation included evaluation of artifacts, spatial resolution, low contrast detectability, noise, and uniformity and CT number accuracy.

Conclusions

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

Based on the conformance to standards, as well as the bench testing provided, Arineta Ltd. believes that the SpotLight Duo is substantially equivalent to the predicate devices, SpotLight CT (K161066) and Revolution CT (K133705).