October 13, 2023

% John Smith
Official Correspondent
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHTINGTON, DC 20004-1109

Re: K230370
Trade/Device Name: SpotLight/SpotLight Duo (with DLIR option)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 8, 2023
Received: September 8, 2023

Dear John Smith:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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OHT8: Office of 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K230370

Device Name

SpotLight / SpotLight Duo (with DLIR option)

Indications for Use *(Describe)*

SpotLight /SpotLight Duo (with DLIR option) 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 cardiovascular and thoracic anatomies, including the heart, in a single rotation. The system may acquire data using Axial, Cine, and Cardiac scan techniques from patients of all ages (DLIR is limited for patient use above the age of 2 years). 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 cardiovascular and thoracic anatomies that fit in the scan field of view. 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)

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510(k) SUMMARY

Arineta's SpotLight Duo (with DLIR option)

K230370

Submitter

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Contact Person: Tanya Shalem, VP of QA&RA

Date Prepared: February 9, 2023

Name of Device: SpotLight / SpotLight Duo (with DLIR option)

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 Device

Device Name	Manufacturer	510(k) Number	Regulation Number	Product Code
SpotLight Duo	Arineta Ltd.	K213465	892.1750	JAK

Device Description

The SpotLight / SpotLight Duo (with DLIR option) 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. The Deep Learning Image Reconstruction (DLIR) algorithm is a deep learning technology-based software sub-system that is integrated into the image reconstruction software. 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.

Intended Use

SpotLight / SpotLight Duo (with DLIR option) is intended for head, body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use

SpotLight / SpotLight Duo (with DLIR option) 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 cardiovascular and thoracic anatomies, including the heart, in a single rotation. The system may acquire data using Axial, Cine, and Cardiac scan techniques from patients of all ages (DLIR is limited for patient use above the age of 2 years). 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 cardiovascular and thoracic anatomies that fit in the scan field of view. The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.

Technological Characteristics

Deep Learning Image Reconstruction (DLIR) is a deep learning technology-based software sub-system that is integrated into the existing image reconstruction chain of the predicate device, SpotLight Duo (K213465), as an alternative to the current cleared ASIR-CV noise reduction algorithm. The intended use of SpotLight Duo (with DLIR option) remains the same as the predicate device SpotLight Duo with ASIR-CV.

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

Technological characteristics	Proposed device - SpotLight / SpotLight Duo (with DLIR option)	Predicate Device – SpotLight Duo (K213465)	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)-20 (EFOV) configurable low resolution (LR). EFOV includes 10 modules on each wing while WFOV includes 10 modules on one wing.	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)-20 (EFOV) configurable low resolution (LR). EFOV includes 10 modules on each wing while WFOV includes 10 modules on one wing.	Same

Technological characteristics	Proposed device - SpotLight / SpotLight Duo (with DLIR option)	Predicate Device – SpotLight Duo (K213465)	Discussion
	comprising 48 detector rows X pitch 2.0mm Analog to digital conversion per channel on the detection module. 1D antiscatter collimator.	comprising 48 detector rows X pitch 2.0mm Analog to digital conversion per channel on the detection module. 1D antiscatter collimator.	
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	Same
Power and control transmission to rotor	Contact less transmission	Contact less transmission	Same
Rotation drive	Direct drive DC motor	Direct drive DC motor	Same
X Ray source	2 x MCS 2093 X ray tubes by Varex Imaging Corp. 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	2 x MCS 2093 X ray tubes by Varex Imaging Corp. 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	Same
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.	Same
Image reconstruction hardware	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). Noise reduction algorithms: ASIR-CV or DLIR AI based image reconstruction algorithm (DLIR only for 250mm FOV and EFOV configuration).	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) to reduce image noise. For WFOV configuration, adapted to reconstruct high resolution images according to detector configuration,	Both devices include ASiR-CV, while the proposed device includes DLIR as an alternative noise reduction algorithm. DLIR can be applied to 250mm FOV and EFOV configuration.

Technological characteristics	Proposed device - SpotLight / SpotLight Duo (with DLIR option)	Predicate Device – SpotLight Duo (K213465)	Discussion
	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.	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.	The SpotLight with DLIR demonstrates the product performance claims (LCD, Noise, High contrast, Spatial resolution, NPS, accuracy and uniformity), as did the SpotLight with ASiR CV.
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 CdWO4 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 CdWO4 and Gadolinium Oxysulfide (GOS) used in other legally marketed CT scanners	Same
Energy sources	Walt 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	Same
Accessories	Head& hands and knees support Optional operator desk (the site may use their own desk) carrying the display monitor, keyboard, mouse, scan operation unit and optional accessories Barcode reader External Console UPS	Head& hands and knees support Optional operator desk (the site may use their own desk) carrying the display monitor, keyboard, mouse, scan operation unit and optional accessories Barcode reader External Console UPS	Same

Technological characteristics	Proposed device - SpotLight / SpotLight Duo (with DLIR option)	Predicate Device – SpotLight Duo (K213465)	Discussion
Software	The SpotLight is provided with software in three domains: • Console software • Image reconstruction software, including the DLIR algorithm • Embedded software	The SpotLight Duo is provided with software in three domains: • Console software • Image reconstruction software • Embedded software	Substantially the same: the software principal block diagram is the same, where the DLIR option is a software sub-system integrated in the existing image reconstruction chain of SpotLight Duo/CardioGraphe as alternative to current the ASIR-CV noise reduction algorithm.
Max Rotation speed	250 RPM (0.24 sec per rotation)	250 RPM (0.24 sec per rotation)	Same
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) – FOV up to 250mm 0.24 sec (full scan) – HR imaging at FOV above 250mm for asymmetric detector	Same
Max axial coverage in a single axial scan	140mm (280 slices x 0.5mm pitch)	140mm (280 slices x 0.5mm pitch)	Same
Field of View (FOV)	25cm - 250mm at high resolution, with DLIR option EFOV – up to 450mm with lower resolution outside FOV 250mm, with DLIR option WFOV - high resolution images at configurable FOV between 250mm and 450mm	25cm - 250mm at high resolution EFOV – up to 450mm with lower resolution outside FOV 250mm WFOV - high resolution images at configurable FOV between 250mm and 450mm	Same as predicate device, except DLIR as optional reconstruction for 25cm and EFOV configurations
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 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	Same
Bore size	60 cm	60 cm	Same
Max Patient weight	227 Kg (500 lbs)	227 Kg (500 lbs)	Same

Non-Clinical Performance Testing

SpotLight is in compliance with the requirements of the following standards:

- IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 - 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 - 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 - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- IEC 62304 Medical device software - Software life cycle processes
- ISO 14971 Medical devices — Application of risk management to medical devices

SpotLight was tested and is in compliance with AAMI/ES 60601-1, IEC 60601-1 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. Image quality evaluation included evaluation of artifacts, spatial resolution, low contrast detectability, noise, uniformity and CT number accuracy.

DLIR bench tests were performed by applying DLIR and ASIR on phantoms: water phantoms, CATPHAN, and QA phantom. Both 250mm and 450mm FOV were tested. As a small body (pediatric), small water phantom was used as well as CATPHAN inserts without the housing, scanned with clinical pediatric protocol. As a large body, large water phantom was used. The tests included image noise (pixel standard deviation), low contrast detectability, water HU accuracy, image flatness (uniformity), spatial resolution, linearity\contrast scale, streak artifact suppression, and noise power spectrum (NPS). Generalizability tests of DLIR in different scan and reconstruction parameters were performed in our bench test. In addition, image quality was performed by applying DLIR and ASIR on clinical data, including evaluation of pixel-wise noise magnitude, HU accuracy and high-contrast edge sharpness, in FOV 250 mm and FOV 450 mm. The bench test results demonstrate that use of DLIR decreases pixel-wise noise magnitude without losing features, changing HU, or reducing High-contrast spatial resolution. The tests performed in this IQ report concluded with passed results and demonstrate that DLIR is substantially equivalent to ASIR in all defined parameters. including pixel-wise noise magnitude, HU accuracy and high-contrast spatial resolution.

Clinical Testing

The proposed DLIR feature was evaluated in a retrospective blinded image evaluation that uses clinical cases acquired by SpotLight / CardioGraphe, using previous software versions. The clinical cases are of different anatomies, using different types of scans, from patients with a wide range of BMIs and clinical features. The data was collected from various SpotLight / CardioGraphe scanners, and the raw data was reconstructed using the DLIR algorithm. Data was collected from multiple clinical sites with at least 50% of the cases performed in the US. Five (5) certified CT readers (3 radiologists and 2 cardiologists. 4 out 5 are US board certified) examined the reconstructed series of different exams. Each exam was reviewed using standard (ASiR-CV) and alternative (DLIR) methods. The data was coded to avoid readers' bias. DLIR was found to provide diagnostic image quality that is not inferior to ASiR (the noise reduction algorithm used in the predicate device, K213465).

Based on non-clinical performance and clinical performance, as documented in the image quality validation testing, the SpotLight has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The SpotLight / SpotLight Duo (with DLIR option) is as safe and effective as the SpotLight Duo with ASiR-CV. SpotLight / SpotLight Duo (with DLIR option) has the same intended use and principles of operation as its predicate device, similar technological characteristics, and updated indications for use. In addition, the minor technological difference between SpotLight / SpotLight Duo (with DLIR option) and its predicate device raises no new issues of safety or effectiveness. Performance data demonstrate that SpotLight / SpotLight Duo (with DLIR option) is as safe and effective as the SpotLight Duo. Thus, SpotLight is substantially equivalent.