January 13, 2025

Arineta Ltd.
% Tanya Shalem
VP QA&RA
15 Halamish St.
Caesarea, 3088900
ISRAEL

Re: K241200
Trade/Device Name: SpotLight/SpotLight Duo with Low Dose Lung Cancer Screening Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 30, 2024
Received: December 13, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241200

Device Name
SpotLight/ SpotLight Duo with Low Dose Lung Cancer Screening Option

Indications for Use *(Describe)*
The SpotLight / 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 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 Low Dose CT Lung Cancer Screening Option for SpotLight / SpotLight Duo is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols (for medium and large patients) that have been approved and published by a governmental body or a professional medical society. Information from professional societies related to lung cancer screening can be found but is not limited to: American College of Radiology® (ACR) – resources and technical specification; accreditation American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information. The DLIR and ASIR-CV algorithms are not compatible with the Low Dose Lung Cancer Screening option.
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (K241200)

Arineta's SpotLight/SpotLight Duo with Low Dose Lung Cancer Screening Option

I. SUBMITTER

Arineta Ltd.
15 Halamish Street
Caesarea 3088900 Israel

Phone: +972-4-6374000

Contact Person: Tanya Shalem, VP of QA&RA, E-mail: tanya.shalem@arineta.com

510k Number: K241200

Date Prepared: January 13, 2025

II. DEVICE

Name of Device: SpotLight/ SpotLight Duo with Low Dose Lung Cancer Screening Option

Common Name: System, X-ray, Tomography, Computed

Classification Name: Computed tomography x-ray system

Regulation Number: 892.1750

Product Code(s): JAK

III. PREDICATE DEVICE

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

Manufacturer: Arineta Ltd.

510(k) Number: K230370

Common Name: System, X-ray, Tomography, Computed

Classification Name: Computed tomography x-ray system

Regulation Number: 892.1750

Product Code(s): JAK

IV. DEVICE DESCRIPTION

The Low Dose Lung Cancer Screening (LD LCS) option is an indication being added to the existing Arineta scanners for SpotLight and SpotLight Duo, previously cleared by the FDA (K230370, K213465).

There are not any functional, performance, feature, or design changes required for the CT systems to which the option is applied.

This option includes scan protocols with CTDI that comply with AAPM's requirements for Low Dose Lung Cancer Screening.

No Hardware modifications and minor Software modifications (for compatibility with the Low-Dose Lung Cancer Screening protocols) are required for the subject device, which includes the following LD LCS protocol characteristics:

• Lung Cancer Screening protocols for medium and large patients according to AAPM's definitions.

• Lung Cancer Screening protocols option will be activated by service or production personnel (no need for additional installation, option activation only).

V. INTENDED USE

The SpotLight Computed Tomography X-ray system is intended for head, body, cardiac and vascular X-ray computed tomography applications.

VI. INDICATIONS FOR USE

The SpotLight / 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 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 Low Dose CT Lung Cancer Screening Option for SpotLight / SpotLight Duo is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols (for medium and large patients) that have been approved and published by a governmental body or a professional medical society. Information from professional societies related to lung cancer screening can be found but is not limited to: American College of Radiology® (ACR) – resources and technical specification; accreditation American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409)

and subsequent literature, for further information. The DLIR and ASIR-CV algorithms are not compatible with the Low Dose Lung Cancer Screening option.

The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.

VII. INDICATIONS FOR USE COMPARISON

The proposed devices do not constitute a new intended use. There is a minor change in the indication for use – the addition of the LD LCS Option, references to ACR and AAPM guidelines, and specific DLIR and ASIR-CV limitations for that option.

VIII. TECHNOLOGICAL COMPARISON

The technological characteristics of the SpotLight/SpotLight Duo with Low Dose Lung Cancer Screening (LD LCS) option and the predicate currently marketed SpotLight/ SpotLight Duo are substantially the same, with no functional, performance, feature, or design changes, except for the added LD LCS scan protocols. The proposed LD LCS option has substantially the same reconstruction technology compared to the predicate currently marketed device. The DLIR and ASIR-CV algorithms are not compatible with the Low Dose Lung Cancer Screening option, as reflected in the Indications for Use.

There is no new technology related to these LCS protocols or their operation. There are no significant differences that may raise new issues of safety or effectiveness. The proposed LD LCS scan protocols have low dose characteristics for medium and large patients and comply with the relevant AAPM CTDI dose values. These parameters were chosen to optimize image quality while minimizing the dose.

The determination of substantial equivalence of the proposed new LD LCS protocols to the cleared predicate device was further evaluated on the bench testing. The new LDCT LCS protocols for Arineta systems were tested and validated by using traditional Image Quality (IQ) metrics on standard phantoms, and compared to the IQ results of the cleared predicate standard dose device. The results indicate maintaining the proposed device's LD LCS protocols for all IQ metrics, including accuracy, uniformity, resolution, contrast scale, and NPS frequencies. Testing was also performed using a semi-anthropomorphic clinical simulation lung phantom where the CNR and nodule sizing comparisons were performed for Arineta systems using their new LDCT LCS protocols. The results showed that the nodules' level of conspicuity and accurate sizing were maintained for the proposed device LDCT LCS protocols. Therefore, it indicated that the proposed devices LD LCS protocols and predicate devices were substantially equivalent.

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

	Proposed devices – **Low Dose CT Lung Cancer Screening (LD LCS) Option for Qualified Arineta Systems**	*Primary Predicate devices* – **The Cleared Arineta's SpotLight / SpotLight Duo (K230370) CT X-ray System (with DLIR option)**	**Discussion**
Indications for Use			
Indications for use	The SpotLight / 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 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 Low Dose CT Lung Cancer Screening Option for SpotLight / SpotLight Duo is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols (for medium and large patients) that have been approved and published by a governmental body or a professional medical society. Information from professional societies related to lung cancer screening can be found but is not limited to: American College of Radiology® (ACR) – resources and technical specification; accreditation American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information. The DLIR and ASIR-CV options are not compatible with the Low Dose Lung Cancer Screening option. The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.	The 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.	The indications for use are similar, with the same indications for the entire device, except for minor differences; the indications for use for the proposed SpotLight/SpotLight Duo devices include Low Dose Lung Cancer Screening Option with additional references to ACR and AAPM guidelines, and specific DLIR and ASIR-CV limitation for that option. LCS indication for use does not constitute a new intended use for the CT.

	***Proposed devices* –** **Low Dose CT Lung Cancer Screening (LD LCS) Option for Qualified Arineta Systems**	***Primary Predicate devices* –** **The Cleared Arineta's SpotLight / SpotLight Duo (K230370) CT X-ray System (with DLIR option)**	**Discussion**
Technological Characteristics			
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. 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. comprising 48 detector rows X pitch 2.0mm Analog to digital conversion per channel on the detection module. 1D antiscatter collimator.	Same
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	Brush contact slipring	Brush contact slipring	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

	***Proposed devices* –** **Low Dose CT Lung Cancer Screening (LD LCS) Option for Qualified Arineta Systems**	***Primary Predicate devices* –** **The Cleared Arineta's SpotLight / SpotLight Duo (K230370) CT X-ray System (with DLIR option)**	**Discussion**
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). Non-local means algorithm MBAF2 (optional). 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). Non-local means algorithm MBAF2 (optional). 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. ASIR-CV or DLIR AI based image reconstruction algorithm.	Substantially the same reconstruction technology, except the ASIR-CV and AI-based DLIR image reconstruction algorithms. The proposed LD LCS option is not compatible with DLIR and ASIR-CV. The LD LCS option is available with or without MBAF2.
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 cable 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	Wall supply 380 to 480 V 3 phase Max power demand 115 kVA Max X ray power (total for two tubes) 72kW	Wall supply 380 to 480 V 3 phase Max power demand 115 kVA Max X ray power (total for two tubes) 72kW	Same

	Proposed devices – **Low Dose CT Lung Cancer Screening (LD LCS) Option for Qualified Arineta Systems**	***Primary Predicate devices –*** **The Cleared Arineta's SpotLight / SpotLight Duo (K230370) CT X-ray System (with DLIR option)**	**Discussion**
	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	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	
Software	Provided with software in three domains: • Console software • Image reconstruction software • Embedded software	Provided with software in three domains: • Console software • Image reconstruction software • Embedded software	Substantially the same, with minor changes in the added LD LCS protocols (for medium and large patients) per AAPM guidelines.
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 WFOV - High resolution images at configurable FOV between 250mm and 450mm EFOV – Lower resolution in the FOV between HR coverage and 450mm	25cm - 250mm at high resolution WFOV - High resolution images at configurable FOV between 250mm and 450mm EFOV – Lower resolution in the FOV between HR coverage and 450mm	Same
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

	***Proposed devices* –** **Low Dose CT Lung Cancer Screening (LD LCS) Option for Qualified Arineta Systems**	***Primary Predicate devices* –** **The Cleared Arineta's SpotLight / SpotLight Duo (K230370) CT X-ray System (with DLIR option)**	**Discussion**
Add on parts and accessories	Operator console table NG2000 Table slickers Bar code reader Uninterruptible Power Supply Head& hands and knees support	Operator console table NG2000 Table slickers Bar code reader Uninterruptible Power Supply Head& hands and knees support	Same
Image Quality Metrics			
CT number accuracy - In a low signal situation such as with LD LCS, the CT number measured in a nodule may be compromised. In LCS, the CT number may be a reference against potentially calcified nodules. CT number uniformity - In a low signal situation such as LD LCS, maintaining sufficient CT number uniformity throughout the lung and various structures is important for more robust detectability of nodules. Uniformity is needed to maintain CT number separation between structures. Image noise (standard deviation) - As dose is reduced, background noise in the image increases. If this noise becomes too large, nodule detectability and sizing measurement may be compromised. Modulation Transfer Function (MTF) - MTF is a measure of the high contrast spatial resolution performance of the system. Nodules in the lung are high contrast objects and therefore, MTF should be preserved at lower dose conditions. Visual Resolution/Image Artifacts - This relates to the evaluation of images to assess their visual resolution using high contrast bar patterns and evaluation of the degree of artifacts (e.g., low signal streaks, beam hardening). These tests are relevant because of the high contrast detection task of relatively small objects for this application. Streak or beam hardening may obscure pathology and affect CT number accuracy. Noise Power Spectrum (NPS) - Similar to standard deviation of noise, changes in noise texture may result in nodule detection becoming more challenging especially if there is a significant shift in the frequency of the noise, and/or an increase in amplitude of the NPS plot. Slice Thickness - The ability to produce slice thicknesses (FWHM of the slice sensitivity profile) that are close to the nominal slice thickness is important in defining clear edges and boundaries of the nodule and in nodule sizing. Contrast to Noise (CNR) - Sufficient CNR is needed to detect solid and non-solid nodules in the lung. This metric is similar to SNR but accounts for the contrast between an object and the background. Arineta believes this is the primary figure of metric to evaluate nodule detectability. The image quality metrics were used for evaluation to determine substantial equivalence. Each metric is provided with a description of the impact/relevance of the metric for LCS. All IQ metrics used for both the proposed and the predicate device are the same.		

IX. NON-CLINICAL TESTING SUMMARY

Arineta Ltd. has conducted extensive bench testing on the Low Dose CT Lung Cancer Screening (LCS) option for the Spotlight and Spotlight Duo CT systems. Additional testing was conducted on Arineta's current qualified SpotLight/SpotLight Duo CT systems cleared in K230370 (the predicate device) and the LCS option of GE Revolution CT (the reference device) for comparison.

Non-clinical tests of the LCS protocols for Spotlight/Spotlight Duo systems have demonstrated that all image quality metrics are substantially equivalent to the predicate:

1. Uniformity and CT numbers for LCS protocols are maintained in the LCS protocol, comparable to the predicate device, and are within ~3 Hounsfield Units.

2. The Noise Power Spectrum (NPS) curve is comparable to the predicate device, with noise reduction slightly shifting the NPS curve to the lower frequencies in both LCS protocol and in the predicate device.

3. Resolution for LCS protocols is maintained compared to the predicate device.

4. Contrast to Noise Ratio (CNR) was measured using the LCS phantom, which includes nodules with different types, HU and sizes. The CNR is linearly related among the LCS protocol and the predicate device, with and without noise reduction (MBAF2). The CNR is comparable to the reference device.

5. All nodule types in the Lung Phantom, including the smallest (4mm) and lowest contrast nodules, are detectable. The nodule size is similar between LCS protocol, predicate, and reference devices, and is according to the LCS phantom specification.

X. CLINICAL TESTING SUMMARY

To confirm that images are clinically acceptable for use, a clinical image quality assessment was performed by two U.S. board-certified radiologists. The data evaluated were collected from two (2) U.S sites and included Low-Dose lung screening exams scanned with Arineta's SpotLight systems. The results show that all fourteen (14) cases, representing medium and large patient sizes per AAPM guidelines (0.25 to 2.8 mGy range has not been clinically evaluated), were evaluated as diagnostic for the indications for use. Moreover, the readers reported various pathologies, including very small nodules (2mm), therefore, the images enable the detection of findings relevant to LD LCS.

Based on the image assessment, it can be concluded that LCS using Low-Dose protocols on the SpotLight/ SpotLight Duo systems generates sufficient diagnostic-quality images.

The clinical image evaluation resulted in the expected detectability of the proposed SpotLight/ SpotLight Duo with LD LCS option, without raising any new safety and/or effectiveness concerns compared to the currently marketed predicate device.

XI. CONCLUSIONS

Based on the Indications for Use and technological characteristics comparisons, non-clinical performance bench testing, and clinical image quality evaluation, the SpotLight/ SpotLight Duo with LD LCS option has a safety and effectiveness profile, that is similar to the predicate device. Thus, the proposed SpotLight/ SpotLight Duo with Low Dose Lung Cancer Screening Option is substantially equivalent to the predicate marketed Arineta's CT systems.