



April 15, 2025

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

Re: K250650

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: March 3, 2025

Received: March 4, 2025

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

A handwritten signature in black ink that reads "Smita Kakar". The signature is written over a large, semi-transparent blue watermark of the letters "FDA".

Lu Jiang  
Assistant Director  
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

## Indications for Use

510(k) Number (if known)

K250650

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 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.

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## **510(k) Summary**

### **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 Q&R, E-mail: tanya.shalem@arineta.com

**510(k) Number:** K250650

**Date Prepared:** Mar 03, 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 Low Dose Lung Cancer Screening Option

**Manufacturer:** Arineta Ltd.

**510(k) Number:** K241200

**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 indication for Arineta's SpotLight and SpotLight Duo scanners is being expanded to include small patients<sup>1</sup>, as defined by AAPM (American Association of Physicists in Medicine). This expansion ensures comprehensive coverage of the intended lung cancer screening population, following the previous clearance of the LD LCS option for medium and large patients under K241200. The proposed LD LCS option for the SpotLight and SpotLight Duo includes scan protocols with CTDI that comply with AAPM's requirements for the whole LD LCS population patient size groups, as detailed in the following table:

Patient Size (AAPM group)	Weight (Kg)	CTDI (mGy)	SpotLight / SpotLight Duo - Indication for Use
Small	50-70 Kg	0.25-2.8 mGy	Proposed Device
Medium	70-90 Kg	0.5-4.3 mGy	K241200
Large	90-120 Kg	1.0-5.6 mGy	K241200

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

The proposed full LD LCS protocols option, as the cleared K241200, will be activated by service or production personnel, with no additional installation required (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.

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<sup>1</sup> Note: The "small patients" subgroup discussed in this submission includes adults eligible for Lung Cancer Screening (LCS) with a weight range of 50 to 70 kg.

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 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 maintain the same intended use. The modification involves a minor update to the indications for use, expanding the Low Dose (LD) Lung Cancer Screening (LCS) patient population to include all relevant groups. This includes the addition of small patient protocols, as defined by AAPM guidelines (50-70 kg, <2.8 mGy).

## **VIII. TECHNOLOGICAL COMPARISON**

The technological characteristics of the SpotLight / SpotLight Duo with whole Low Dose Lung Cancer Screening (LD LCS) option and the predicate SpotLight / SpotLight Duo are substantially the same, with no functional, performance, feature, or design changes.

There is no new technology related to LCS protocols or their operation, and no significant differences that may raise new issues of safety or effectiveness. Similarly to the predicate device cleared for medium and large patients' protocols, the LD LCS scan protocols for small patients comply with the relevant AAPM CTDI dose values, chosen to optimize image quality while minimizing the dose.

The proposed LD LCS option has the same reconstruction technology, and the DLIR and ASIR-CV algorithms are not compatible with both the predicate and proposed device LD LCS option, as reflected in the Indications for Use.

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

	<p align="center"><b>Proposed devices – Low Dose CT Lung Cancer Screening (LD LCS) Option for the SpotLight / SpotLight Duo System <u>(Whole LCS population indication- small, medium, and large patient groups)</u></b></p>	<p align="center"><b>Primary Predicate devices – The Cleared Arineta’s SpotLight / SpotLight Duo (K241200) CT X-ray System with Low Dose Lung Cancer Screening (LD LCS) Option <u>(LCS medium and large patient groups indication)</u></b></p>	<p align="center"><b>Discussion</b></p>
<b>Indications for Use</b>			
<p><b>Indications for use</b></p>	<p>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.</p> <p>The system is indicated for x-ray Computed Tomography imaging of cardiovascular and thoracic anatomies that fit in the scan field-of-view.</p> <p>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 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.</p> <p>The DLIR and ASIR-CV options are not compatible with the Low Dose Lung Cancer Screening option.</p> <p>The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.</p>	<p>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.</p> <p>The system is indicated for x-ray Computed Tomography imaging of cardiovascular and thoracic anatomies that fit in the scan field-of-view.</p> <p>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 <b>(for medium and large patients)</b> 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.</p> <p>The DLIR and ASIR-CV options are not compatible with the Low Dose Lung Cancer Screening option.</p> <p>The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.</p>	<p>The indications for use are similar except for minor differences. The indications for use for the proposed SpotLight/SpotLight Duo devices include the whole Low Dose Lung Cancer Screening Option with additional small patient protocols per AAPM guidelines (50-70kg, &lt;2.8 mGy).</p> <p>The indication for use does not constitute a new intended use for the CT.</p>

	<b><i>Proposed devices – Low Dose CT Lung Cancer Screening (LD LCS) Option for the SpotLight / SpotLight Duo System (Whole LCS population indication- small, medium, and large patient groups)</i></b>	<b><i>Primary Predicate devices – The Cleared Arineta’s SpotLight / SpotLight Duo (K241200) CT X-ray System with Low Dose Lung Cancer Screening (LD LCS) Option (LCS medium and large patient groups indication)</i></b>	<b>Discussion</b>
<b>Technological Characteristics</b>			
Detector technology and geometry	<p>Fast scintillator array coupled to photodiode array.</p> <p>33 (WFOV) or 23 (EFOV) configurable high resolution (HR) modules comprising 192 detector rows X pitch 0.5mm (Z direction, measured at scanner center).</p> <p>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</p> <p>Analog to digital conversion per channel on the detection module.</p> <p>1D antiscatter collimator.</p>	<p>Fast scintillator array coupled to photodiode array.</p> <p>33 (WFOV) or 23 (EFOV) configurable high resolution (HR) modules comprising 192 detector rows X pitch 0.5mm (Z direction, measured at scanner center).</p> <p>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</p> <p>Analog to digital conversion per channel on the detection module.</p> <p>1D antiscatter collimator.</p>	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	<p>2 x MCS 2093 X ray tubes by Varex Imaging Corp.</p> <p>Single ended grounded rotating anode</p> <p>Anode angle 13 degrees</p> <p>1.0 MHU anode heat capacity</p> <p>Grid controlled focal spot modulation in X direction</p> <p>Small and large focal spots</p> <p>Max kVp: 140 kV</p> <p>Max power: 72 KW</p>	<p>2 x MCS 2093 X ray tubes by Varex Imaging Corp.</p> <p>Single ended grounded rotating anode</p> <p>Anode angle 13 degrees</p> <p>1.0 MHU anode heat capacity</p> <p>Grid controlled focal spot modulation in X direction</p> <p>Small and large focal spots</p> <p>Max kVp: 140 kV</p> <p>Max power: 72 KW</p>	Same
Patient table	<p>Motorized vertical and horizontal motion.</p> <p>Optional lateral motion</p> <p>Cantilever carbon fiber patient cradle.</p>	<p>Motorized vertical and horizontal motion.</p> <p>Optional lateral motion.</p> <p>Cantilever carbon fiber patient cradle.</p>	Same

	<b><i>Proposed devices – Low Dose CT Lung Cancer Screening (LD LCS) Option for the SpotLight / SpotLight Duo System (Whole LCS population indication- small, medium, and large patient groups)</i></b>	<b><i>Primary Predicate devices – The Cleared Arineta’s SpotLight / SpotLight Duo (K241200) CT X-ray System with Low Dose Lung Cancer Screening (LD LCS) Option (LCS medium and large patient groups indication)</i></b>	<b>Discussion</b>
Image reconstruction hardware	Multicore PC and GPU	Multicore PC and GPU	Same
Image reconstruction algorithm	<p>Modified FDK cone beam algorithm adapted for dual tubes geometry.</p> <p>Adaptive filter to reduce directional noise in low level raw data (MBAF).</p> <p>Non-local means algorithm MBAF2 (optional).</p> <p>For WFOV configuration, adapted to reconstruct high resolution images according to detector configuration, lower resolution images outside FOV covered by high resolution detectors.</p> <p>For extended FOV configuration, adapted to reconstruct high resolution images up to FOV250mm, lower resolution images outside FOV250mm.</p>	<p>Modified FDK cone beam algorithm adapted for dual tubes geometry.</p> <p>Adaptive filter to reduce directional noise in low level raw data (MBAF).</p> <p>Non-local means algorithm MBAF2 (optional).</p> <p>For WFOV configuration, adapted to reconstruct high resolution images according to detector configuration, lower resolution images outside FOV covered by high resolution detectors.</p> <p>For extended FOV configuration, adapted to reconstruct high resolution images up to FOV250mm, lower resolution images outside FOV250mm.</p>	Same
Construction Materials	<p>Metal parts (mostly steel and aluminum)</p> <p>Lead and tungsten for X-ray shielding</p> <p>PCB, electronic components and electronic cables components</p> <p>Table top made of carbon fiber reinforced resin</p> <p>Covers made pf molded polymers and reinforced resins</p> <p>Oil in X-ray tubes cooling systems</p> <p>Detector scintillators made of CdWO<sub>4</sub> and Gadolinium Oxysulfide (GOS) used in other legally marketed CT scanners</p>	<p>Metal parts (mostly steel and aluminum)</p> <p>Lead and tungsten for X-ray shielding</p> <p>PCB, electronic components and electronic cable components</p> <p>Table top made of carbon fiber reinforced resin</p> <p>Covers made pf molded polymers and reinforced resins</p> <p>Oil in X-ray tubes cooling systems</p> <p>Detector scintillators made of CdWO<sub>4</sub> and Gadolinium Oxysulfide (GOS) used in other legally marketed CT scanners</p>	Same
Energy sources	<p>Wall supply 380 to 480 V 3 phase</p> <p>Max power demand 115 kVA</p> <p>Max X ray power (total for two tubes) 72kW</p>	<p>Wall supply 380 to 480 V 3 phase</p> <p>Max power demand 115 kVA</p> <p>Max X ray power (total for two tubes) 72kW</p>	Same

	<b><i>Proposed devices – Low Dose CT Lung Cancer Screening (LD LCS) Option for the SpotLight / SpotLight Duo System (Whole LCS population indication- small, medium, and large patient groups)</i></b>	<b><i>Primary Predicate devices – The Cleared Arineta’s SpotLight / SpotLight Duo (K241200) CT X-ray System with Low Dose Lung Cancer Screening (LD LCS) Option (LCS medium and large patient groups indication)</i></b>	<b>Discussion</b>
	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: <ul style="list-style-type: none"> <li>• Console software</li> <li>• Image reconstruction software</li> <li>• Embedded software</li> </ul>	Provided with software in three domains: <ul style="list-style-type: none"> <li>• Console software</li> <li>• Image reconstruction software</li> <li>• Embedded software</li> </ul>	Same
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

	<b><i>Proposed devices –</i></b> <b>Low Dose CT Lung Cancer Screening (LD LCS) Option</b> <b>for the SpotLight / SpotLight Duo System</b> <b><u>(Whole LCS population indication-</u></b> <b><u>small, medium, and large patient groups)</u></b>	<b><i>Primary Predicate devices –</i></b> <b>The Cleared Arineta’s SpotLight / SpotLight Duo</b> <b>(K241200) CT X-ray System with Low Dose Lung Cancer</b> <b>Screening (LD LCS) Option</b> <b><u>(LCS medium and large patient groups indication)</u></b>	<b>Discussion</b>
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

## **IX. NON-CLINICAL TESTING / CLINICAL TESTING SUMMARY**

No additional non-clinical testing is required for the inclusion of small patient protocols to the Low Dose (LD) CT Lung Cancer Screening (LCS) option for the Spotlight and Spotlight Duo CT systems. The bench testing that supported the clearance of K241200 has demonstrated adequate performance across all LD LCS protocols, including the low-dose range (<2.8 mGy) used to acquire images on small patients. The lowest dose protocol (<2.8 mGy) tested on phantoms, maintained image quality and nodule detectability.

To extend the SpotLight LD LCS indications to small patients, additional clinical testing supporting data was evaluated under the same clinical protocol of the cleared K241200.

The large and medium patient size groups (>70 kg), as defined by AAPM, included in the cleared K241200 clinical assessment, were identified as the 'worst-case' scenario for performance evaluation. This designation was based on increased X-ray attenuation with an expected reduction in image quality for larger patients, and the predominance of larger patients within the LD LCS-eligible population distribution.

To confirm that small patient LCS group images (50-70kg, <2.8 mGy) 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 3 U.S sites and included Low-Dose lung screening exams scanned with Arineta's SpotLight / SpotLight Duo systems. The clinical testing sample size included data from 10 additional small patient exams, aligning with the patient distribution in the cleared K241200, which comprised 7 medium and 7 large-size patient cases. Including these additional small patient evaluations, supplemented with the 14 larger patient datasets from K241200, provides a comprehensive assessment across the LCS-eligible patient population, encompassing small, medium, and large patient sizes.

The results show that all 10 cases, representing small patient sizes per AAPM, 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 small patient Low-Dose protocols (50-70kg, <2.8 mGy) 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 for small patient protocols, without raising any new safety and/or effectiveness concerns compared to the current medium and large patient protocols LD LCS predicate device.

## **X. CONCLUSIONS**

The additional clinical performance data for small patients and the extensive bench testing (covered in K241200 for all protocols) support the safe and effective use of the device for the complete LD LCS-eligible intended patient population.

Based on the indications for use and technological characteristics comparisons, the SpotLight/ SpotLight Duo with LD LCS option for small patients is as safe and effective as the predicate device with LD LCS option for medium and large patients. Thus, the proposed SpotLight / SpotLight Duo with the whole Low Dose Lung Cancer Screening Option is substantially equivalent to the predicate cleared Arineta's CT systems.