December 19, 2025

LEADOPTIK Inc.
% Lorry Weaver
Principal Consultant
Qserve Group
350 S. Main Street, Suite 309,
Doylestown, Pennsylvania 18901

Re: K251730
Trade/Device Name: LIA Console (542-7)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: June 5, 2025
Received: June 6, 2025

Dear Timothy Joiner:

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,

JESSICA CARR -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251730

Device Name
LIA Console (542-7)

Indications for Use *(Describe)*
The LIA Console is indicated for use as an imaging tool in the evaluation of human tissue microstructure in the tracheobronchial tree by providing two-dimensional, cross-sectional, real-time depth visualization using Optical Coherence Tomography (OCT).

The safety and effectiveness of this device for diagnostic analysis (i.e., differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated

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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Section 5: 510(k) Summary – [21 CFR 807.92]

807.92(a)(1), (2), (3)

Date Prepared: December 12, 2025

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Device Trade Name: LIA Console

Common Name: Optical Coherence Tomography (OCT) Imaging System

Review Panel: General & Plastic Surgery/Radiology

Classification Name: Ultrasonic pulsed echo imaging system

Regulation No.: 892.1560

Classification Code: NQQ

Predicate Device: NvisionVLE Imaging System: 510(k) K182616
Classification Code: NQQ
Regulation: 892.1560

Device Description *807.92(a)(4)***:**

The LIA Console is indicated for use as an imaging tool in the evaluation of human tissue microstructure in the tracheobronchial tree by providing two-dimensional, cross-sectional, real-time depth visualization using Optical Coherence Tomography (OCT). The LIA Console is intended to be used only in conjunction with the LIA-1 Catheter in order to function as intended.

LIA Console consists of the following main parts:

1. **Monitor:** 24-inch multi-touch display monitor allowing software user interface.
2. **Catheter Driving Unit (CDU):** Electromechanical and optical interface between the LIA Console and the LIA-1 Catheter. A rotary motor inside drives the LIA-1 Catheter to form 360-degree side view real-time imaging.
3. **Catheter Driving Arm (CDA):** A supporting arm allowing CDU positioning, mobility and flexibility during the procedure.
4. **Image Engine:** The main body of the LIA Console contains laser source, computing unit, data acquisition and power distribution module and other components.

5. **Caster:** Four caster wheels installed at the base provide mobility for the LIA Console. Each caster is equipped with a brake that can lock the LIA Console in place as needed.
6. **OCTICA Software:** A proprietary GUI-based software that controls data acquisition, rotary motor and other hardware components to enable real-time OCT imaging of tissue microstructure.

Indications for Use *[Intended Use 807.92(a)(5)]***:**

The LIA Console is indicated for use as an imaging tool in the evaluation of human tissue microstructure in the tracheobronchial tree by providing two-dimensional, cross-sectional, real-time depth visualization using Optical Coherence Tomography (OCT). The safety and effectiveness of this device for diagnostic analysis (i.e., differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.

Technological Characteristics *807.92(a)(6)***:**

The LIA Console is an imaging tool for the evaluation of human tissue microstructure using Optical Coherence Tomography (OCT). The system is not intended for diagnostic differentiation. Swept Source Optical Coherence Tomography (SS-OCT) is the method for real-time cross-sectional imaging, supporting tissue evaluation.

The LIA Console consists of (i) an imaging console, (ii) a catheter driving arm, and (iii) proprietary LIA Real-Time Imagine Software used to acquire, process, and visualize OCT images. It is used in conjunction with a compatible LIA-1 Catheter during the endobronchial biopsy procedure.

The mobile imaging console contains a light source, interferometer, and computing unit. It processes optical signals received from the LIA-1 Catheter to generate and display real-time images on the monitor.

The Catheter Driving Arm (CDA) includes an articulating stabilization arm and a driving module including an optical receptacle to which the LIA-1 is connected. The driving module drives the imaging stylet to form a 360-degree 2D image. The arm stabilizes the imaging probe throughout the procedure.

The Catheter Driving Unit (CDU) serves as the optomechanical interface between the LIA-1 Catheter and the imaging engine. It includes a Fiber Optical Rotary Joint (FORJ) that transmits optical signals to the LIA-1 Catheter and receives the backscattered signal after interaction with tissue. The FORJ, in conjunction with a motor, also rotates LIA-1 Catheter's optical probe to generate a 360-degree image.

As shown in Table 1 below, the LIA Console is substantially equivalent to the predicate devices, as it has the same intended use and its technological characteristics are similar to, and substantially equivalent to, the cited predicates.

Table 1. Predicate Comparison

Devices	Subject Device LIA Console (K251730)	Predicate Device NvisionVLE® Imaging System (K182616)
Regulation Product Code	892.1560 NQQ	892.1560 NQQ
Indications for Use	The LIA Console is indicated for use as an imaging tool in the evaluation of human tissue microstructure in the tracheobronchial tree by providing two-dimensional, cross-sectional, real-time depth visualization using Optical Coherence Tomography (OCT). The safety and effectiveness of this device for diagnostic analysis (i.e., differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.	The NvisionVLE® Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue. The software provides segmentation and display of common imaging features, including hyper-reflective surface, layering, and hypo-reflective structures. The NvisionVLE® Imaging System is intended to provide an image of tissue microstructure. The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.
Device Description	The LIA Console is indicated for use as an imaging tool in the evaluation of human tissue microstructure in the tracheobronchial tree by providing two-dimensional, cross-sectional, real-time depth visualization using Optical Coherence Tomography (OCT). LIA Console is intended to be used only in conjunction with the LIA-1 Catheter in order to function as intended. LIA Console consists of the following main parts: (1) Monitor: 24-inch multi-touch display monitor allowing software user interface. (2) Catheter Driving Unit (CDU): Electromechanical and optical interface between the LIA Console and the LIA-1 Catheter. A rotary motor inside drives the LIA-1 Catheter to form 360-degree side view real-time imaging. (3) Catheter Driving Arm (CDA): A supporting arm allowing CDU positioning, mobility and flexibility during the procedure. (4) Image Engine:	The NinePoint Medical NvisionVLE® Imaging System is a high-resolution volumetric imaging system based on optical coherence tomography (OCT). In an analogous fashion to ultrasound imagery, OCT images are formed from the time delay and magnitude of the signal reflected from the tissue of interest. The NvisionVLE Imaging System employs an advanced form of OCT known as sweptsource OCT (SS-OCT), or Optical Frequency Domain Imaging (OFDI), in combination with a scanning optical probe to acquire high-resolution, cross-sectional, real-time imagery of tissue called Volumetric Laser Endomicroscopy (VLE). In addition to the imaging capability, the device provides a means of marking areas of tissue with an additionally integrated 1470 nm laser. The ability to create temporary

	The main body of the LIA Console contains laser source, computing unit, data acquisition and power distribution module and other components. (5) Caster: Four caster wheels installed at the base provide mobility for the LIA Console. Each caster is equipped with a brake that can lock the LIA Console in place as needed. (6) OCTICA Software: A proprietary GUI software that controls data acquisition, rotary motor and other hardware to enable real-time OCT imaging of tissue microstructure.	laser marks directly on tissue enables a clinician to place visual reference marks on tissue regions of clinical interest immediately following their identification via VLE. The device consists of the following five main components and accessories: (i) a mobile NvisionVLE Console with an integrated computer and two touch-screen interfaces; (ii) proprietary NvisionVLE Software used to acquire, process, and visualize VLE images; (iii) a single-use, sterile NvisionVLE Marking Probe that is inserted through the working channel of an endoscope; (iv) a single-use, sterile NvisionVLE Inflation System that is used to inflate the Marking Probe's balloon to facilitate placement; and (v) a Probe Lock Accessory to prevent longitudinal motion of the Marking Probe within the endoscope.
Imaging Modality	Swept-Source OCT (SS-OCT)	Swept-Source OCT (SS-OCT)
System Components	Imaging System reusable electrical mechanical unit. Disposable imaging catheter.	Imaging System reusable electrical mechanical unit. Disposable imaging catheter.
Primary Functions	Delivers energy (infrared light) to the tissue. Measures the depth and pattern of reflections from the tissue from the return near infrared light to create high-resolution, real-time images. Stores images for evaluation and review	Delivers energy (infrared light) to the tissue. Measures the depth and pattern of reflections from the tissue from the return near infrared light to create high-resolution, real-time images. Stores images for evaluation and review
Software	OCTICA – IEC 62304	Proprietary, artificial intelligent technology
Image Creation, Display and Storage	Process reflected optical signals to construct images. Display images. Store images.	Process reflected optical signals to construct images. Volumetric Laser Endomicroscopy (VLE), Display images. Store images.
Imaging Probe	Single use	Single use
A-line rate	100 kHz	20 kHz
Laser Center Wavelength	1300 nm	1305 nm
Console Features	Mobile Console	Mobile Console
Safety	ES60601-1:2005(R)2012	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2
Optical/laser safety	IEC 60825-1:2014 to be a Class 1M Laser Product	IEC 60825-1

Summary of Non-Clinical Test - Performance and Safety Testing *807.92(b)(1)*:

LIA Console was evaluated and found to meet performance standards and requirements for general safety, electrical, electromagnetic, transportation and software development.

Electrical Safety and EMC

LIA Console meets the requirements of the relevant elements of the following electrical safety and EMC standards.

- **ANSI/AAMI ES 60601-1:2005 [Including Amendment 2 (2021)] & EN/IEC60601-1-6:2013** Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

- **IEC 60601-1-2:2014/AMD1:2020** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Packaging / Distribution Testing

LIA Console has been tested and follows ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems.

Laser Classification

LIA Console has been determined under IEC 60825-1:2014 to be a Class 1M Laser Product.

Fluid Ingress Testing

LIA Console has been tested under IEC 60529, Edition 2.2 - 2013-08 and classified as IPX1.

Service Life Testing

The service life of the LIA Console is expected to be 3 years from the date of installation.

Software Testing

LIA Console and Application Software (OCTICA) were developed and tested in compliance with IEC 62304. Software verification and validation were conducted to FDA regulations, standards, and guidance document requirements. The results of this testing conclude the software has met these requirements.

Bench Testing

LEADOPTIK Inc. performed a series of bench tests to demonstrate LIA Console meets its performance specifications using production-equivalent, finished, product. Comprehensive verification and validation activities were successfully completed,

raising no new issues of safety or effectiveness. Tests included, but not limited to, OCT sensitivity characterization, service life, fluid ingress, lateral and axial resolution, NURD measurement, optical power efficiency, metalens field profile analysis. All testing passed the acceptance criteria.

Summary of Pre-clinical Tests *807.92(b)(1)*:

A GLP porcine study with Fiducial Lung Nodule (FLN, ≤20mm) was conducted to evaluate human tissue microstructure in the tracheobronchial tree. Thirty two FLNs were administrated into airway system of two pigs (16 FLNs per animal). The data show that LIA System (LIA Console and LIA-1 Catheter) can provide real-time imaging of tissue microstructure in the tracheobronchial tree with diameters ranging from 1mm-10mm. Additionally, the data show the biopsy success rate using the LIA System was 100% for all 32 FLNs. There were no complications found during the study.

Therefore, the GLP porcine study concludes LIA System is substantially equivalent to the predicate device and meets the intended use.

Summary of Clinical Tests *807.92(b)(2)*:

Clinical performance testing was not required as simulated use validation demonstrated intended use performance.

Conclusion *807.92(b)(3)*:

LIA Console and the predicate device, NvisionVLE® Imaging System (K182616) are both devices that “project a beam into body tissue to determine the depth or location of the tissue interfaces” according to regulation 892.1560. Both devices are specifically Optical Coherence Tomography (OCT) imaging systems within product code NQQ.

The indications for use and key technological characteristics are substantially equivalent employing swept source Optical Coherence Tomography (SS-OCT) imaging modalities and ensuring comparable real-time tissue visualization for clinical applications

LIA Console was evaluated for electrical, optical, mechanical, and EMC safety and found to conform to applicable mandatory medical device safety standards.

The differences between the devices do not raise new and/or different questions of safety and effectiveness. LIA Console conforms to applicable safety standards and performance data in a simulated clinical workflow (including in K251402, LIA-1 Catheter) validates the intended use. The predicate comparison table (Table 1) and performance testing provided in this 510(k) is sufficient to demonstrate that the LIA Console is substantially equivalent to the legally marketed predicate device, NvisionVLE® Imaging System cleared under 510(k) K182616.