December 19, 2025

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

Re: K251402
Trade/Device Name: LIA-1 Catheter (542-1)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: November 20, 2025
Received: November 20, 2025

Dear Lorry Weaver:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251402

Please provide the device trade name(s).

LIA-1 Catheter (542-1)

Please provide your Indications for Use below.

The LIA-1 Catheter is intended for use through a compatible bronchoscope in the tracheobronchial tree for Optical Coherence Tomography (OCT) guided Fine Needle Aspiration (FNA) and Fine Needle Biopsy (FNB) of endobronchial lesions, peripheral lung nodules, and lung masses. The device collects real-time two-dimensional, cross-sectional depth images which are visualized for evaluation of human tissue microstructure on the LIA Console.

Do not use this device for any purpose other than its intended use. This device is intended to provide an image of tissue microstructure in the tracheobronchial tree and parenchyma. 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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-1 Catheter

Common Name: Bronchoscope and accessories

Review Panel: Ear, Nose, and Throat

Classification Name: Bronchoscope (flexible or rigid) and accessories

Regulation No.: 874.4680

Classification Code: KTI

Predicate Device: ViziShot 2 FLEX: 510(k) K193517
Regulation: 874.4680
Classification Code: KTI

Reference Device: iNod Ultrasound Guided Biopsy Needle K221340
Regulation: 874.4680
Classification Code: EOQ

Reference Device: PeriView FLEX K181193
Regulation: 874.4680
Classification Code: KTI

Device Description *807.92(a)(4)*:
LIA-1 Catheter is a sterile, single-use, Optical Coherence Tomography (OCT) image-guided biopsy needle which is an assembly consisting of a Handle, Outer Sheath, Needle, and Imaging Stylet (iStylet). The Outer Sheath and Needle are attached to Actuation Handle and the iStylet is located within the Needle.

Outer Sheath: The LIA-1 Catheter Outer Sheath consists of a clear tube attached to the Handle.

Handle: The LIA-1 Catheter Handle allows the user to actuate the needle from the distal tip of the Outer Sheath, and to actuate the iStylet into or out of the Needle tip, or to be retracted for biopsy collection, as necessary.

Needle: The 21G stainless-steel Needle has a beveled, sharpened tip for puncture and tissue collection.

Imaging Stylet: The iStylet consists of a shaft and imaging core serving as an optical imaging probe. It provides real-time imaging for its intended use.

The LIA-1 Catheter is intended to be used only in conjunction with the LIA Console in order to function as intended.

Indications for Use *[Intended Use 807.92(a)(5)]***:**
The LIA-1 Catheter is intended for use through a compatible bronchoscope in the tracheobronchial tree for Optical Coherence Tomography (OCT) guided Fine Needle Aspiration (FNA) and Fine Needle Biopsy (FNB) of endobronchial lesions, peripheral lung nodules, and lung masses. The device collects real-time two-dimensional, cross-sectional depth images which are visualized for evaluation of human tissue microstructure on the LIA Console.

Do not use this device for any purpose other than its intended use. This device is intended to provide an image of tissue microstructure in the tracheobronchial tree and parenchyma. 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 type of imaging guidance utilized in the subject device is different than in the predicate device. The regulation (874.4680) does not put limitations on what type of imaging can be utilized to guide a transbronchial needle biopsy. Both devices are image-guided and are used in a similar fashion. The LIA-1 Catheter may be used together with a compatible ultrasound endoscope (however, this is not required).

LIA-1 Catheter identifies tissue to be biopsied are endobronchial lesions, peripheral lung nodules, or lung masses whereas the predicate device (ViziShot 2 FLEX) identifies submucosal and extramural lesions of the tracheobronchial tree. These tissue are similar in characteristics across them all and are located in the respiratory pathways. Additional differences between the devices include the stylet outer diameter (OD), working length, and the needle gauge sizes supplied with the device. LIA-1 Catheter iStylet is slightly larger (0.0260”) than the stylet (0.0204”) of ViziShot 2 FLEX. Its working length is longer (110 cm) and the needle gauge is smaller (21G) compared to its counterpart predicate device (70 cm for working length and 19G for needle gauge). However, those parameters are the same as their counterparts in the Reference device, PeriView FLEX (K181193) for similar intended use (collection of tissue from the intrapulmonary regions).

These differences do not introduce new or different issues of safety and effectiveness.

Table 1. Predicate Comparison

Devices	Subject Device LIA-1 Catheter (K251402)	Predicate Device ViziShot 2 FLEX (K193517)	Reference Device iNod Ultrasound Guided Biopsy Needle (K221340)
Regulation **Product Code**	874.4680 KTI	874.4680 KTI	874.4680 EOQ
Intended Use	Image guided fine needle aspiration and fine needle biopsy through a bronchoscope.	The ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.	Image guided fine needle aspiration through a bronchoscope.
Indications for Use	The LIA-1 Catheter is intended for use through a compatible bronchoscope in the tracheobronchial tree for OCT guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of endobronchial lesions, peripheral lung nodules, or lung masses. The device collects real-time two-dimensional, cross-sectional depth images which are visualized for evaluation of human tissue microstructure on the LIA-1 Console. Do not use this device for any purpose other than its intended use. This device is intended to provide an image of tissue microstructure in the tracheobronchial tree. 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 ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.	The iNod Ultrasound Guided Biopsy Needle is intended for use through a flexible bronchoscope for intraluminal sonographic imaging in the tracheobronchial tree and retrieval of specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Devices	Subject Device LIA-1 Catheter (K251402)	Predicate Device ViziShot 2 FLEX (K193517)	Reference Device iNod Ultrasound Guided Biopsy Needle (K221340)
Device Description	LIA-1 Catheter is a sterile, single-use, Optical Coherence Tomography (OCT) image-guided biopsy needle which is an assembly consisting of a Handle, Outer Sheath, Needle, and Imaging Stylet (iStylet). The Outer Sheath and Needle are attached to Actuation Handle and the iStylet is located within the Needle. Outer Sheath: The LIA-1 Catheter Outer Sheath consists of a clear tube attached to the Handle. Handle: The LIA-1 Catheter Handle allows the user to actuate the needle from the distal tip of the Outer Sheath, and to actuate the iStylet into or out of the Needle tip, or to be retracted for biopsy collection, as necessary. Needle: The 21G stainless-steel Needle has a beveled, sharpened tip for puncture and tissue collection. Imaging Stylet: The iStylet consists of a shaft and imaging core serving as an optical imaging probe. It provides real-imaging for its intended use. The LIA-1 Catheter is intended to be used only in conjunction with the LIA Console in order to function as intended.	The subject device, ViziShot 2 FLEX is a single use aspiration needle to be used in conjunction with compatible ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. The subject device consists of a handle, sheath, needle, and stylet. The sheath and needle are attached to the handle, and the removable stylet is located within the needle. Note that although, the device has a component called a needle, the device is often referred to as a needle as well. The device is a single-use sterile device. Prior to a procedure, the flexible catheter portion is inserted into a bronchoscope's working channel (2.2mm) and advanced forward until fully inserted. The handle is then affixed to the channel port of the endoscope via a lever mechanism that locks onto the Adapter Biopsy Valve. The needle is advanced through the bronchoscope to the sampling site while visualizing both the target and the needle in real time with ultrasound. The handle facilitates advancement of the needle during puncture of the targeted biopsy site. The sample is obtained by penetrating the lesion with the needle while applying suction at the proximal end of the handle. After completing the sampling, the vacuum from the syringe is released to atmosphere, the handle unlocked	The proposed iNod Ultrasound Guidance System (iNod System), comprises: the sterile, single use iNod Ultrasound Guided Biopsy Needle (also referred to as iNod Single Use Device (SUD), iNod Ultrasound Guidance Console (iNod Console) and the iNod Motor Drive Unit (iNod MDU). The proposed iNod Ultrasound Guidance System is intended to perform pulmonary needle biopsy under real-time visualization using Radial Endobronchial Ultrasound (R-EBUS). The iNod single-use-device (iNod SUD) is a single use, sterile device that has combined functionality of a radial ultrasound probe and a biopsy needle. The iNod SUD allows real-time visualization of pulmonary lesions with radial ultrasound, while simultaneously allowing biopsy of the pulmonary lesions. The three main parts of iNod SUD are a handle, a radial ultrasound transducer, and biopsy needle. The biopsy needle is actuated at an angle that allows biopsy of eccentric and concentric nodules. A stainless-steel needle indicator strip is housed in the imaging window at distal tip, which provides an ultrasound signature, indicating the orientation of the needle to the user in the ultrasound image. The biopsy needle will exit the iNod SUD distal tip at 180 degrees relative to the needle indicator position visible in the ultrasound image. Once the needle is positioned to biopsy a nodule, the needle is unlocked by user to the exit ramp at 11° angle. Finally, when a

Devices	Subject Device LIA-1 Catheter (K251402)	Predicate Device ViziShot 2 FLEX (K193517)	Reference Device iNod Ultrasound Guided Biopsy Needle (K221340)
		from the bronchoscope, and the catheter and needle pulled out from the working channel. The removed tissue can then be prepared for cytopathological or microbiological examination and testing. The ViziShot 2 FLEX is available in one model only (NA-U403SX-4019), with a needle size of 19 gauge (19G). The two required accessories, the Adapter Biopsy Valve and the Merit Syringe with Stopcock, are packaged with the ViziShot 2 FLEX.	sample is collected, the Nitinol stylet can be passed down the needle lumen to expel the sample.
Imaging Technology	Optical Coherence Tomography (OCT)	Ultrasound	Radial Endobronchial Ultrasound (R-EBUS)
Use Conditions	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Same	Same
Mechanism of Action	Manual	Same	Same
Mode of Action	Single/multiple puncture and aspirate	Same	N/A
General Design	Handle, Sheath, Needle, Stylet	Handle, Sheath, Needle, Stylet	Handle, a radial ultrasound transducer and biopsy needle.
Single Use Only	Yes	Yes	Yes
Working OD (mm)	1.50	2.08	Not Publicly Available
Compatible Working Channel (mm)	≥1.7mm	2.2	2.0

Devices	Subject Device LIA-1 Catheter (K251402)	Predicate Device ViziShot 2 FLEX (K193517)	Reference Device iNod Ultrasound Guided Biopsy Needle (K221340)
Working Length (cm)	110	70	117
Needle Gauge	21G	19G	25G
Typical Needle Length (mm)	20	20	Not publicly available
Max Needle Length (mm)	40	40	25
Stylet OD (Inch)	0.0260	0.0204	N/A
Stylet Surface Finish	Polished	Polished	N/A
Sterilization	E-beam	Ethylene Oxide	E-beam

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

LIA-1 Catheter was evaluated and performed in compliance with external standards and internal design control procedures including Biocompatibility, Sterilization and shelf life, bench test, pre-clinical animal test, and summative usability test to demonstrate substantial equivalence to its predicate device.

Biocompatibility

The LIA-1 Catheter was classified as an externally communicating device with tissue and limited contact duration (<24 hours). In accordance with FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"” and International Standard ISO 10993-1, ISO10993-5, ISO10993-10, ISO10993-11, ISO10993-23 the following tests were performed.

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous Reactivity
4. Acute Systemic Toxicity
5. Material-Mediated Pyrogenicity

All tests passed the acceptance criteria, and the test reports were determined to support the biocompatibility of the device for its indication of use.

Sterilization and Shelf-life

Sterilization validation was performed to ensure a SAL of 10^{-6}, according to international sterilization standards; ISO11137-1, ISO 11137-2, ISO 11137-3, ISO 11137-4, ISO 11737-1, ISO 11737-2.

Shelf-life: accelerated aging was performed. LIA-1 Catheter passed the (T=0, T=12 accelerated aging) package performance testing which includes sterilization, climatic conditioning, package performance, visual inspections, aseptic transfer, gross leak detection (bubble), and seal strength (peel) of the LIA-1 Catheter applicable acceptance criteria according to national packaging standards ASTM D4332, ASTM D4169, ASTM F1886, ASTM F2096, ASTM F88, ASTM F1929, ISO11607-1.

All tests passed the acceptance criteria. The LIA-1 Catheter sterile barrier system maintains sterility integrity over 12 months accelerated aging time.

Bench Testing

LEADOPTIK Inc. performed a series of bench tests including visual inspection, lateral and axial resolution, NURD testing, optical power efficiency testing, image field of view, imaging depth of field, metalens field profile analysis, needle coring capability, dimensional inspection, bronchoscope compatibility testing, fatigue cycle testing, tensile strength testing etc. to verify design specification of LIA-1 Catheter using production-equivalent, finished, sterilized, and pre-conditioned products. All tests passed the acceptance criteria.

Summative Usability Test

A summative usability study was conducted to assess the human factor of LIA-1 Catheter being used for the intended use by the intended users per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" (Issued on: February 3, 2016). All tests passed the acceptance criteria, and the test reports were determined to support substantial equivalence to the predicate device.

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-1 Catheter and the predicate device, ViziShot 2 FLEX (K193517) have the same indications for use and similar technological characteristics. OCT and ultrasound are both imaging modalities to achieve visualization of tissue. Differences between the devices do not raise new and/or different questions of safety and effectiveness. LIA-1 Catheter conforms to applicable safety standards and performance data in a simulated clinical workflow, when used with the LIA Console. Performance testing provided in this 510(k) is sufficient to demonstrate that the LIA-1 Catheter is substantially equivalent to the legally marketed predicate device, ViziShot 2 FLEX cleared under 510(k) K193517.