May 14, 2026

Elucent Medical
Jake Burke
Regulatory Affairs Manager
6509 Flying Cloud Dr.
Suite 160
Eden Prairie, Minnesota 55344

Re: K260565
Trade/Device Name: SmartClip Delivery Catheter (ADR-1715)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 19, 2026
Received: February 19, 2026

Dear Jake Burke:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

John S. Bender -S

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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)*
K260565

Device Name
SmartClip Delivery Catheter

Indications for Use *(Describe)*
SmartClip Delivery Catheter is to be utilized through a flexible bronchoscope by physicians trained in endoscopic techniques to puncture the tracheobronchial wall and to facilitate the delivery and placement of an Elucent SmartClip soft tissue marker within the lung parenchyma at a target site. The device is used in situations where the lung tissue site needs to be marked for future diagnostic or therapeutic 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.

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510(k) Summary

Applicant Name: Elucent Medical

Applicant Address: 6509 Flying Cloud Drive Suite 160 Eden Prairie MN 55344 United States

Applicant Contact: Mr. Jake Burke

Applicant Contact Telephone: 651-210-2813

Applicant Contact Email: jake.burke@elucent.com

Device Trade Name: SmartClip Delivery Catheter (ADR-1715)

Common Name: Bronchoscope (Flexible or Rigid)

Classification Name: Bronchoscope (flexible or rigid) and accessories

Regulation Number: 21 CFR 874.4680

Product Codes: EOQ

Legally Marketed Predicate Device: K142934 – CrossCountry Transbronchial Access Tool - EOQ

Device Description Summary:
The Catheter Delivery System is a single-use, terminally sterilized (EO) device used by a physician, trained in bronchoscopic techniques, to facilitate the placement of SmartClip soft tissue markers (SmartClips). The Catheter Delivery System consists of a flexible sheath, a stylet with a tapered distal tip, and a handle.

The outer sheath, containing the inner stylet is traversed through a 2.0mm or greater working channel of a bronchoscope to the target tissue intended to be marked by a SmartClip. The stylet is used to puncture the tracheobronchial wall, and the outer sheath is advanced into the tissue to maintain access to the implantation site. The SmartClip is then deposited into the proximal end of the catheter and deployed to the target site by the stylet.

Intended Use/Indications for Use:
SmartClip Delivery Catheter is to be utilized through a flexible bronchoscope by physicians trained in endoscopic techniques to puncture the tracheobronchial wall and to facilitate the delivery and placement of an Elucent SmartClip soft tissue marker within the lung parenchyma at a target site. The device is used in situations where the lung tissue site needs to be marked for future diagnostic or therapeutic procedures.

Indications for Use Comparison:
The subject and predicate devices share the same intended use. While the indications for use of the subject and predicate vary slightly, the differences do not constitute a new intended use. The subject and predicate devices are both intended to traverse through an endoscope, puncture the tracheobronchial wall using a sharp tipped component, maintain access to the target lung tissue with a catheter, and facilitate placement of markers or endoscopic tools to the target site.

Technological Comparison

The subject device shares several technological characteristics as the predicate device including:

- Design: A flexible catheter and sharp tipped component used for puncturing the tracheobronchial wall
- Materials: Sterile, single-use, biocompatible materials
- Principle of Operation: A catheter and sharp tipped component are traversed through an endoscope, the sharp tip punctures the tracheobronchial wall and the catheter maintains access to the within the lung parenchyma.
- Energy Source: Mechanical

Description	**Subject Device: SmartClip Delivery Catheter**	**Predicate Device: CrossCountry (K142934)**	**Comments**
Intended Use	Facilitate access, via a channel, to enable placement of a SmartClip soft tissue marker	Facilitate access, via a channel, to enable placement of endoscopic tools, including fiducial markers	Directly comparable Both devices facilitate access to the lung parenchyma to enable fiducial marker placement
Indications for Use	SmartClip Delivery Catheter is to be utilized through a flexible bronchoscope by physicians trained in endoscopic techniques to puncture the tracheobronchial wall and to facilitate the delivery and placement of an Elucent SmartClip soft tissue marker within the lung parenchyma at a target site. The device is used in situations where the lung tissue site needs to be marked for future diagnostic or therapeutic procedures.	The CrossCountry transbronchial access tool is to be utilized through a flexible endoscope with an extended working channel by physicians who are trained in endoscopic techniques to puncture the tracheobronchial wall and facilitate access of additional endobronchial tools for patients with endobronchial lesions, peripheral lung nodules, or lung masses.	Directly comparable Both devices are utilized via a flexible endoscope to puncture the tracheobronchial wall and to facilitate access to the lung parenchyma.
Principle of Operation	The SmartClip Delivery Catheter is composed primarily of a stylet and catheter. The stylet is used to pierce a hole through the tracheobronchial wall, traversing the lung parenchyma into the targeted site. The catheter is advanced through the lung parenchyma to maintain access to the lung parenchyma. The stylet is then used to facilitate placement of a SmartClip soft tissue marker within the lung parenchyma.	The CrossCountry is composed primarily of a guidewire and catheter. The guidewire is used to pierce a hole through the tracheobronchial wall, traversing the lung parenchyma into the desired site of implantation. The dilation catheter is advanced over the guidewire and introduced into the target lesion to maintain access within the lung parenchyma.	Directly comparable Both devices utilize a sharp tipped component to puncture the tracheobronchial wall and a catheter component to maintain access within the lung parenchyma.

Patient Contacting Components	Stylet and Catheter	Wire and Catheter	Directly comparable The stylet of the subject device and wire of the predicate device share the same function: to mechanically puncture the tracheobronchial wall
Working Outer Diameter (OD)	Catheter OD: 1.79mm Stylet: 1.40mm	Catheter OD: 2.01mm Wire OD: 0.66mm	Directly comparable Differences in the OD of the catheter (0.22mm), and stylet and wire (0.74mm) do not impact the overall performance or clinical functionality.
Working Length	Catheter: 115.6cm Stylet: 124.4cm	Catheter: 109.9cm Wire: 116.1cm	Directly comparable Differences in the working length of the catheter (5.7cm), stylet and wire (8.3cm) do not impact overall performance or clinical functionality.
Working Outer Material	Outer Sheath: Pebax	Polymer – Copolyester Elastomer Braid – 304 Stainless Steel	Directly comparable Materials are biocompatible
Stylet/Wire Material	Stylet: High-Density Polyethylene (HDPE)	Tip: Titanium Wire: Nitinol	Directly comparable Materials are biocompatible

In summary, the subject SmartClip Delivery Catheter has similar technology and principle of operation as the predicate device.

Non-Clinical Tests Summary
The following performance data were provided in support of the substantial equivalence determination between the subject SmartClip Delivery Catheter and the CrossCountry transbronchial access tool.

Biocompatibility: Conducted in accordance with ISO 10993-1 and FDA Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

- Cytotoxicity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Sensitization
- Irritation

Design Verification and Validation:

- Functional Testing
- Inspections Testing
- Shelf Life Testing
- Packaging Testing
- Distribution Testing
- Sterilization Validation
- Human Factors and Usability Testing

Animal Study:
A preclinical study was conducted using the SmartClip Delivery Catheter. All acceptance criteria were met. This study demonstrated the SmartClip Delivery Catheter is able to meet its intended use.

Clinical Testing:
Clinical data were not necessary to support a determination of substantial equivalence.

Non-Clinical Tests Conclusion
In summary, verification testing conducted demonstrated that the subject SmartClip Delivery Catheter meets defined specification and is substantially equivalent to the predicate CrossCountry Transbronchial Access Tool.

Conclusion (Statement of Equivalence):
Elucent Medical has demonstrated that the proposed SmartClip Delivery Catheter is substantially equivalent to the CrossCountry transbronchial access tool which is legally marketed for the same intended use. The non-clinical test data and the in vivo animal study provide adequate justification to demonstrate that the SmartClip Delivery Catheter is substantially equivalent to the predicate device.