October 8, 2025

Serpex Medical, Inc.
Diane Horwitz
Regulatory Consultant
3350 Scott Blvd.
Suite 37B
Santa Clara, California 95054

Re: K252874
Trade/Device Name: Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: September 9, 2025
Received: September 10, 2025

Dear Diane Horwitz:

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,
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

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.	K252874

Please provide the device trade name(s).

Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01

Please provide your Indications for Use below.

The Compass Steerable Needle is a steerable transbronchial biopsy needle intended to be used through a compatible working channel bronchoscope or Medtronic Extended Working Channel (EWC) for the collection of tissue from the intrapulmonary regions.

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)

serpex

510(k) SUMMARY

1. SUBMITTER INFORMATION

Submitter:

Serpex Medical, Inc.
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Official Correspondent:

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Date Prepared: September 9, 2025

2. DEVICE INFORMATION

Proprietary Name:	**Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01**
Common/Usual Name:	Aspiration Needle
Classification Name:	Bronchoscope Accessory
Regulatory Class:	Class II
Product Code:	KTI
Regulation Number:	21 CFR 874.4680

3. Predicate Device Information

Proprietary Name:	**Compass Steerable Needle**
Common/Usual Name:	Aspiration Needle
Classification Name:	Bronchoscope Accessory
510K Number:	K221206

4. Device Description

The Compass Steerable Needle (CSN) is sterile, single use, 22-gauge transbronchial needle with a unidirectional, steerable distal tip for the acquisition of tissue from the intrapulmonary regions. The Compass Steerable Needle include two model numbers, Model CSN1001 and Model CSN1002. Model CSN1001 includes two accessory adapters for attachment to bronchoscopes.

The subject of this 510(k) is the addition of two new adapters to Model CSN1002. Adapter SRA-1-01 connects the Model CSN1002 to the Ion™ Endoluminal System, and Adapter SRA-2-01 connects the Model CSN1002 to the Monarch™ Platform or Galaxy System™.

5. Intended Use/Indication for use

The Compass Steerable Needle is a steerable transbronchial biopsy needle intended be used through a compatible working channel bronchoscope or Medtronic Extended Working Channel (EWC) for the collection of tissue from the intrapulmonary regions.

6. Comparison of Technological Characteristics

The Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01 is substantially equivalent to the Compass Steerable Needle cleared under K221206. The adapters to the Model CSN1002 (SRA-1-01 and SRA-2-01) connect the CSN1002 to robotic bronchoscopes to obtain tissue from intrapulmonary regions. The Compass Steerable Needle device is unchanged.

	Subject Device Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01	**Predicate Device Compass Steerable Needle K221206**	**Same or Different**
Intended Use	To collect tissue from the intrapulmonary regions.	To collect tissue from the intrapulmonary regions.	Same
Indications for use	The Compass Steerable Needle is a steerable transbronchial biopsy needle intended be used through a compatible working channel bronchoscope or Medtronic Extended Working Channel (EWC) for the collection of tissue from the intrapulmonary regions.	The Compass Steerable Needle is a steerable transbronchial biopsy needle intended be used through a compatible working channel bronchoscope or Medtronic Extended Working Channel (EWC) for the collection of tissue from the intrapulmonary regions.	Same
Connecting Devices	Unchanged previous connecting device under K221206 <u>CSN1002</u> Added two new adapters to connect to the following bronchoscopes: • Ion™ Endoluminal System bronchoscope • Monarch™ Platform bronchoscope • Galaxy System™ bronchoscope	<u>CSN1001</u> Olympus 190 or Pentax bronchoscope 600mm length 2.0mm working channel <u>CSN1002</u> Medtronic Illumisite EWC 1070mm length, 2.0mm working channel	Similar. Though the connecting bronchoscopes are different, the Compass Steerable Needle serves the same functional role - to obtain tissue samples using the same method. Connections have been demonstrated to meet specifications in bench testing.
Sterilization	EtO Adapters in sterile single-use pouches; shelf box contains 10 pouches	EtO Compass Steerable Needle and accessory adapters in sterile single use shelf tray.	Same; both have single use sterile package

7. SUMMARY OF NON-CLINICAL TESTING

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971: 2019. The design verifications tests and their acceptance criteria were identified and performed with passing results.

Bench testing was performed with the Compass Steerable Needles with Adapters SRA-1-01 and SRA-2-01 using sterile finished devices at t=0 and aged time points. Testing supported that all product requirements and specifications were met and demonstrated substantial equivalence. Testing included:

- Sterilization
- Packaging and labeling
- Dimensional
- Functional pre- and post-simulated use
- Tensile

The following standards have been applied to the Compass Steerable Needle Adapters:

- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- ISO 11607-2 Packing for Terminally Sterilized Medical Devices
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ANSI AAMI ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for development, validation, and routine control of a sterilization process for medical devices
- ANSI/AAMI ST72: 2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
- USP-NF <151> Pyrogen Test
- ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ASTM F1886/ FM1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1980-21 Accelerated aging
- ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials

Testing demonstrated that all endpoints were met.

8. CONCLUSION

The Compass Steerable Needle with Adapters SRA-1-01 and SRA-2-01 are substantially equivalent to the Compass Steerable Needle (K221206) in intended use, indications for use, technological characteristics, and performance testing. Substantial equivalence has been demonstrated.