August 25, 2022

Serpex Medical, Inc.
% Laurie Lewandowski
Vice President
Honkanen Consulting, Inc.
738 Saddle Wood Drive
Eagan, Minnesota 55123

Re: K221206
Trade/Device Name: Compass Steerable Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: July 22, 2022
Received: July 25, 2022

Dear Laurie Lewandowski:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Brandon Blakely, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221206

Device Name
Compass Steerable Needle

Indications for Use *(Describe)*
The Compass Steerable Needle is a steerable 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.

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

1. SUBMITTER INFORMATION

Submitter:
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DATE PREPARED:
August 25, 2022

2. DEVICE INFORMATION

Proprietary Name:	**Compass Steerable Needle**
Common/Usual Name:	Aspiration Needle
Classification Name:	Bronchoscope Accessory
Regulatory Class:	Class II
Product Code:	KTI
Regulation Number:	21 CFR 874.4680

3. PREDICATE AND REFERENCE DEVICE INFORMATION

PRIMARY PREDICATE DEVICE:

Proprietary Name:	PeriView Flex
Common/Usual Name:	Aspiration Needle
Classification Name:	Bronchoscope Accessory
510K Number:	K171232

SECONDARY PREDICATE DEVICE:

Proprietary Name:	Ion™ Endoluminal System; Flexision™ Biopsy Needle
Common/Usual Name:	Aspiration Needle
Classification Name:	Bronchoscope (Flexible or Rigid) and Accessories
510K Number:	K182188

REFERENCE DEVICE:

Proprietary Name:	Morrison Steerable Needle
Common/Usual Name:	Biopsy Needle
Classification Name:	Instrument, Biopsy
510K Number:	K151396

4. DEVICE DESCRIPTION

The Compass Steerable Needles (CSN) are sterile, single use, 22-gauge needles with a unidirectional, steerable distal tip for the acquisition of tissue from the intrapulmonary regions.

The Steerable Needle consists of a handle, shaft, and needle. The handle provides the user with control of device rotation, extension, retraction, distal tip articulation of 70°±10° unidirectionally within a plane and a sampling mechanism to extend and retract the needle out of the shaft to obtain tissue samples. A Luer connector on the proximal end of the device provides the connection for the stylet or a syringe for aspiration during sampling. There are two models of the Compass Steerable Needle.

Model CSN1001 can be coupled to Olympus® 190 or Pentax® bronchoscopes with a 2.0 working channel and 600 mm working length. It is packaged with a stylet, and adapters.

Model CSN1002 can be coupled to the Medtronic Illumisite™ Extended Working Channel (EWC) with a 2.0 mm working channel. It is packaged with a stylet.

The Compass Steerable Needles with stylet are inserted and coupled to either a bronchoscope or a Medtronic Illumisite EWC. The translation arm advances the device into the lung. Depressing the plunger articulates the distal end of the shaft. The sampling mechanism is depressed extending the needle to obtain a sample.

5. INTENDED USE/INDICATION FOR USE

The Compass Steerable Needle is a steerable 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 Needles have the same basic technological characteristics as the primary predicate, PeriView Flex, cleared under K171232 with a Franseen shaped needle and the ability to articulate and couple to bronchoscopes. The secondary predicate Ion™ Endoluminal System; Flexision™ Biopsy Needle (K182188) and the reference device, the Morrison Biopsy Needle (K151396) were used to support articulation and needle size. The subject and predicate devices all operate in the same manner to obtain tissue during sampling in the lungs.

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A comparison of the Compass Steerable Needles and the PeriView Flex are shown in the following table with a discussion following.

Attribute	Proposed Device Compass Steerable Needle	PeriView Flex K171232 Primary Predicate	Difference and Impact on Substantial Equivalence
Intended Use	To collect tissue from the intrapulmonary regions.	Identical	SE
Indications for use	The Compass Steerable Needle is a steerable 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.	This device is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions. Do not use for any purpose other than its intended use.	SE Similar to primary predicate with minor wording differences
Users	Clinicians trained in bronchoscopy devices, accessories, and procedures	Identical	SE
Anatomic Site	Lung	Identical	SE
Method of Introduction	Endobronchial delivered to the target through a flexible endoscope or EWC.	Endobronchial delivered to the target through a flexible endoscope or EWC.	SE
Required Working Channel	2mm	2mm	SE
General Design	Handle, Shaft, Needle, Stylet, Adapters	Handle, Sheath, Needle, Stylet	SE Adapters to couple the device.
Needle Size	22G	21G	SE
Needle Tip	Franseen	Chiba (angled beveled)	See discussion
Needle Protrusion Length	15 mm	20 mm	See discussion
Coupling	Coupled to bronchoscope	N/A	See discussion
Mode of Sampling Action	Single / multiple puncture and aspirate manually controlled	Single / multiple puncture and aspirate manually controlled	SE
Angle of Articulation	Shaft articulates 70º in a single direction	N/A	See discussion
Dimensions	Shaft OD ≤ 1.93mm Working Length: CSN1001 715-800mm; CSN1002 1035-1085mm	Shaft OD = 1.5mm Total Length = 115cm	SE All work within a 2.0 bronchoscope or working channel
Stylet OD	0.43mm	0.47 mm	SE

Attribute	Proposed Device Compass Steerable Needle	PeriView Flex K171232 Primary Predicate	Difference and Impact on Substantial Equivalence
			Both stylets fit inside needle
Radiopaque	Yes	Yes	SE
Life/Sterility	Single Use, EO sterilized	Identical	SE
Patient Contacting Materials	Pebax Vestamid Stainless steel PET Heat Shrink Nitinol	Stainless Steel, PTFE, Pebax, Nitinol	SE All devices comprised of standard medical device materials
Biocompatible	Yes, conforms to 10993-1	Yes, conforms to 10993-1	SE

Discussion: The Compass Steerable Needles are the same as the primary predicate in terms with the exception of the needle gauge, needle tip, protrusion, articulation and coupling to a bronchoscope.

The needle size is substantially equivalent to the secondary predicate, the Flexision with needle sizes of 23G, 21G and 19G and reference device, the Morrison needle at 19G.

Franseen needle tips have been used for lung biopsy devices for > 20 years as supported by devices K770523 Needle Biopsy, Boyd Lung, and the Merit Medical Temno Elite Biopsy System (K201166).

The protrusion length is of the Compass Steerable Needle is within the same range as the secondary predicate, Flexision, of 1-3 cm.

The Compass Steerable Needle articulates the distal shaft $70^{o} \pm 10^{o}$ in a single direction. The secondary predicate articulates the catheter 180^{o} in all directions using electromechanical controls while the reference device articulates in two directions using manual controls.

Coupling of devices to a bronchoscope has previously been cleared in ultrasound bronchoscopes as supported by Olympus ViziShot 2 EBUS-TBNA (K193527).

The different technological characteristics of the new device do not raise different questions of safety and effectiveness.

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7. PERFORMANCE DATA

Bench Testing – pre and post aging

Test	Method	Results
Visual	Inspect with the naked eye or under a X scope	Devices met acceptance criteria
Dimensional	Measure: OD, ID, Length, Needle Throw, Articulation Length, Stylet Protrusion Length, Stylet OD, Travel, Retraction	Devices met acceptance criteria
Force – Insertion, plunger and sampling mechanism	Measure insertion force into the scope; force to depress plunger/sampling mechanism with Instron	Devices met acceptance criteria
Articulation	Measure angle, length, curve profile, stability and planarity	Devices met acceptance criteria
Tensile	Tensile test all joints and coupling	Devices met acceptance criteria
Adapter Vacuum/pneumostasis	Ability to hold a vacuum of 20 Hg mercury	Devices met acceptance criteria
Needle Leak	Flush 5ml saline, inspect for leak	Devices met acceptance criteria
Durability	Condition device simulating use during a procedure, visual, articulation and functional	Devices met acceptance criteria
Bending/Buckling	Measure bending and buckling force	Devices met acceptance criteria
Torque Transmission / Integrity	Measure peak torque at 90° rotation / no joint separation after 720 ° rotation	Devices met acceptance criteria
Lumen patency needle	Ensure stylet can be inserted	Devices met acceptance criteria
Corrosion resistance	Test per ISO 10555-1:2013	Devices met acceptance criteria
Packaging	Distribution per ASTM D4169:2016 Aging per ASTM F1980:2016, Packaging per ISO 11607-1:2019 Visual per ASTM F1886/F1886M-16 Bubble Leak per ASTM F2096-11:2019 Seal Strength per ASTM F88/F88M-15	Packages met accept criteria

The test results demonstrated that differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.

Validation testing

Validation testing was performed demonstrating the Compass Steerable Needles user needs and intended use were met. Testing under simulated use conditions was performed in accordance with the Instructions for Use. Human cadavers were used to demonstrate

clinical performance within the human lung anatomy. Cadaver testing demonstrated the Compass Steerable Needles Instructions for Use are understandable, and the device meets the intended use no new risks identified.

Human Factors Usability

Formative studies were conducted to identify and minimize use errors related to the use of the Compass Steerable Needles. Studies were conducted by intended user groups in a simulated bronchoscopy suite and involved preoperative preparation and simulated procedures. Since the user interface of the device is similar to the predicate device and the formative studies did not identify any new critical tasks unique to the device, a limited Summative Validation with study was conducted. The Instructions for Use and Reference Guide were assessed in the usability study. The Compass Steerable Needles has been assessed and found to be safe and effective for its intended use, by the intended users, in its intended use environment.

Biocompatibility

Biocompatibility testing was performed in accordance with:

- ISO 10993-1:2018 for a limited (<24 hour) tissue contacting device and
- FDA Guidance: "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," September 2020

Testing demonstrated that all endpoints were met.

Sterilization:

Sterilization (ethylene oxide) and packaging of the Compass Steerable Needles were validated using the following standards:

- ANSI/AAMI/ISO 11607-1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI/AAMI/ISO 11135:2014 Sterilization of health-care products – ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- FDA Guidance: Submission and Review of Sterility Information in Pre-Market Notification 510(k) Submissions for Device Labeled as Sterile (January 21, 2016)

Testing demonstrated that all endpoints were met.

8. CONCLUSION

The Compass Steerable Needles are substantially equivalent in terms of the indications for use, technological characteristic, performance testing and comparison to the cited predicates, and do not present any new questions of safety and effectiveness.