August 15, 2022

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

Re: K221302
Trade/Device Name: Recon Steerable Sheath
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 14, 2022
Received: July 15, 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 Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K221302

Device Name
Recon Steerable Sheath

Indications for Use *(Describe)*
The Recon Steerable Sheath is an extended working channel intended to be used with a compatible bronchoscope to guide endotherapy accessories to the target area within the respiratory system.

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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serpex

510(k) SUMMARY

1. SUBMITTER INFORMATION

Submitter:
Serpex Medical, Inc.
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DATE PREPARED:
May 4, 2022

2. DEVICE INFORMATION

Proprietary Name:	**Recon Steerable Sheath**
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Common/Usual Name:	Guide Catheter
Regulatory Class:	Class II
Product Code:	EOQ
Regulation Number:	21 CFR 874.4680

3. PREDICATE DEVICE INFORMATION

Proprietary Name:	Lung Vision Tool
Common/Usual Name:	Guide Catheter
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulatory Class:	Class II
Product Code:	EOQ
Regulation Number:	21 CFR 874.4680
510K Number:	K172955

4. DEVICE DESCRIPTION

The Recon Steerable Sheath is a sterile, single use transbronchial sheath with a unidirectional, steerable distal tip that provides access to the intrapulmonary regions. It is

designed to guide endotherapy tools with an outer diameter of up to 1.9 mm and minimum length of 1100 mm to the target tissue.

The Recon Steerable Sheath (Model RSS1000) includes the Steerable Sheath, Stylet, Bronchoscope Adapter and Pentax Adapter.

The Recon Steerable Sheath is compatible with Olympus® 190 or Pentax® bronchoscopes that have a 2.8mm working channel and 600 mm working length. It is coupled to the selected bronchoscope using an adapter(s).

The handle provides the user with control of device rotation, extension, retraction, and distal tip articulation of 90º minimum within a plane with the stylet inserted. A Luer connector on the proximal end of the device provides the connection for the stylet.

The Recon Steerable Sheath with stylet is inserted and coupled to a bronchoscope via a clip on the handle. The telescope advances the device beyond the bronchoscope into the lung. Depressing the plunger articulates the distal end of the sheath by tensioning an internal pull wire. Once in the desired location, the Stylet is removed from the Steerable Sheath and the tool of choice can be inserted for access.

5. INTENDED USE/INDICATION FOR USE

The Recon Steerable Sheath is an extended working channel intended to be used with a compatible bronchoscope to guide endotherapy accessories to the target area within the respiratory system.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Recon Steerable Sheaths have the same technological characteristics as the predicate, Lung Vision Tool, cleared under K172955. The subject and predicate device both provide a path for endotherapy tools to reach target tissue.

A comparison of the Recon Steerable Sheath and the Lung Vision Tool is in the following table.

Attribute	Proposed Device Recon Steerable Sheath	Body Vision Lung Vision Tool K172955 Predicate	Difference and Impact on Substantial Equivalence
Intended Use	To guide endoscopic tool*s* to target tissue	Identical	Identical to predicate

Attribute	Proposed Device Recon Steerable Sheath	Body Vision Lung Vision Tool K172955 Predicate	Difference and Impact on Substantial Equivalence
Indications for use	The Recon Steerable Sheath is an extended working channel intended to be used with a compatible bronchoscope to guide endotherapy accessories to the target area within the respiratory system.	LungVision Tool is an instrument designed as a working channel intended to be used with standard bronchoscopes, endotherapy accessories and ultrasound probe to guide the endotherapy accessories or ultrasound probe to the target area, specifically within the respiratory system.	Similar to predicate; minor wording differences including the use of an ultrasound probe for guiding for the predicate
Users	Clinicians trained in bronchoscopy devices, accessories, and procedures	Identical	Identical to predicate
Anatomic Site	Lung	Identical	Identical to predicate
Method of Introduction	Delivered through a flexible bronchoscope	Identical	Identical to predicate
Recommended Channel Size	2.8 mm	Identical	Identical to predicate
Components	Handle, Shaft, Stylet, Adapters	Handle, Sheath, Stylet, Adapters	Identical to predicate
Compatible Bronchoscope Size	2.8 mm	Identical	Identical to predicate
Articulation / Curve	Manual articulation (depress plunger) to articulate the distal tip a minimum of 90º	Preformed curve shapes of 90° and 210°	Similar Subject device articulates to 90º, the same articulation as one of the preformed curves.
Extension	Yes 140mm	Yes Not listed	Identical to predicate
Extension beyond scope with device retracted	≤ 10 mm	17 mm	Similar

Attribute	Proposed Device Recon Steerable Sheath	Body Vision Lung Vision Tool K172955 Predicate	Difference and Impact on Substantial Equivalence
Outer Diameter	≤ 2.73mm	≤ 2.72mm	Similar Both are intended to fit within a 2.8 mm bronchoscope
Inner Diameter	≥1.93mm	≥2.08mm	Similar – accommodates endotherapy tools up to 1.90mm
Total Length	1095 mm ± 5 mm	1000mm	Similar
Stylet OD	1.83 mm ± 0.05 mm	Not listed	Sized to fit sheath
Radiopaque	Yes	Yes	Identical to predicate
Life/Sterility	Single Use, EO sterilized	Identical	Identical to predicate
Biocompatible	Yes	Yes	Identical to predicate

The Recon Steerable Sheath has the same intended use, similar indications for use with the ability to articulate distal tip 90º minimum unidirectionally to reach target tissue. The angle of articulation is identical to one of the preformed curve shapes of the predicate device. The clinician manually articulates the subject device and manually manipulates the predicate device to reach target tissue.

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

7. PERFORMANCE DATA

Bench Testing

All testing was performed pre and post aging.

- Visual
- Dimensional
- Insertion force
- Articulation angle, length, curve profile, curve stability, and planarity
- Coupling Tensile
- Tensile for all bonds/joints
- Bronchoscope Adapter Pneumostasis / Adapter Vacuum,
- Simulated Use / Device robustness
- Plunger force
- Bending, Buckling
- Torque Transmission and Integrity
- Lumen Patency

Packaging

Packaging was subjected to Environmental, Distribution Simulation and Aging with testing performed pre and post aging

Distribution, Environmental and Aging of Packages

- Distribution per ASTM D4169:2016
- Environmental Conditioning per ISTA 3A:2011
- Aging per ASTM F1980:2016,
- Packaging per ISO 11607-1:2006
  - Visual per ASTM F1886-16/F1886M-16
  - Bubble Leak per ASTM F2096-11:2019
  - Seal Strength per ASTM F88/F88M-15

Packages met the specifications pre and post aging.
All tests met the predefined acceptance 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 Recon Steerable Sheath user needs and intended use were met. Testing under simulated use conditions was performed in accordance with the Instructions for Use. The Recon Steerable Sheath met the performance requirements and was found to be clinically acceptable by all evaluators.

Usability

A human factors (HF) engineering process was followed in accordance with the following:

- ANSI/AAMI/IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices
- FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff," 2016

Formative and summative validation studies were conducted to identify and minimize use errors related to the use of the Recon Steerable Sheath. Studies were conducted by intended user groups in a simulated bronchoscopy suite and involved preoperative preparation and simulated procedures. The Instructions for Use and Reference Guide were assessed in the usability study. No new use errors were identified. The Recon Steerable Sheath 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," June 2016

The following testing was performed:

- Cytotoxicity: MEM Extraction Cytotoxicity Assay per ISO 10993-5:2009/ (R) 2014
- Sensitization: Guinea Pig Maximization Test per ISO 10993-10:2010 / (R) 2014
- Irritation: Intracutaneous Reactivity Test, per ISO10993- 23:2021
- Toxicity: Acute Systemic Toxicity per ISO 10993-11:2017
- Toxicity: Materials Medicated Rabbit Pyrogen Test ISO 10993-11:2017
- Pyrogen testing per USP 39 <151>
- Bacterial Endotoxin Testing per USP 39 <85>

Sterilization:

Sterilization (ethylene oxide) and packaging of the Recon Steerable Sheaths 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 11135-1:2014 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)
- AAMI ST72:2011/(R)2016 Bacterial Endotoxins - Test Methods, Routine Monitoring,
- ISO 10993-7:2008 Amendment 1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

Testing demonstrated that all endpoints were met.

8. CONCLUSION

The Recon Steerable Sheath is substantially equivalent in terms of the indications for use, technological characteristics, performance testing and comparison to the cited predicate, and does not present any new questions of safety and effectiveness.