DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Veran Medical Technologies, Inc.
% Mr. Scott Wrightstone
Director of QA/RA
1908 Innerbelt Business Center Drive
ST. LOUIS MO 63114

May 15, 2017

Re: K170023
Trade/Device Name: SPiN Thoracic Navigation System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 1, 2017
Received: May 3, 2017

Dear Mr. Wrightstone:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170023

Device Name
SPiN Thoracic Navigation System

Indications for Use *(Describe)*
The SPiN Thoracic Navigation System is a stereotactic accessory for Computed Tomography (CT) and endoscopic bronchoscope systems. The SPiN Thoracic Navigation System is indicated for displaying:
• An interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based model of the target organ(s).
• Images of the tracheobronchial tree to aid a physician in guiding endoscopic tools, catheters or guidewires in the pulmonary tract.
The SPiN Thoracic Navigation System compensates for the patient's respiratory phases.

The SPiN Thoracic Navigation System is intended for use in clinical interventions and for anatomical structures where computed tomography and/or endoscopic bronchoscopy are currently used for visualizing such procedures.

The SPiN Thoracic Navigation System enables marker placement in soft lung tissue.

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)

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510(k) Summary
Veran Medical Technologies
Traditional 510(k)
SPiN Thoracic Navigation System

1. Submitter

510(k) Submitter:
Veran Medical Technologies, Inc.
1908 Innerbelt Business Center Drive
St. Louis, MO 63114

Contact:
Scott Wrightstone
Director of Quality Assurance & Regulatory Affairs
Phone: 314-659-8500
Fax: 314-659-8560

Date Prepared:

December 9, 2016

2. Subject Device

Trade Name:	SPiN Thoracic Navigation System
Common Name:	CT stereotactic accessory, Bronchoscope
Classification Name:	Computed Tomography X-ray System, Bronchoscope Accessory, Bronchoscope (Flexible or Rigid) 21 CFR 892.1750
Classification Code:	JAK, LLZ
Manufacturer:	Veran Medical Technologies, Inc.

3. Predicate Devices

Primary Predicate

Trade Name:	SPiN Drive
Common Name:	CT stereotactic accessory
510(k):	K122106
Classification Name:	Computed Tomography X-ray System 21 CFR 892.1750
Classification Code:	JAK
Manufacturer:	Veran Medical Technologies, Inc.

Secondary Predicate

Trade Name:	inReach System
Common Name:	Bronchoscope
510(k):	K081379
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Manufacturer:	superDimension, LTD

4. Device Description

The SPiN Thoracic Navigation System is an accessory for a CT system that utilizes electromagnetic tracking technology to locate and navigate endoscopic tools, catheters and guidewires relative to a CT-based model of the tracheobronchial tree. Due to system use to locate structures in soft tissue, the system incorporates a method of gating the location information on soft tissue to the patient's respiration. The SPiN Thoracic Navigation System consists of an EM tracking accessory, a patient referencing system, an EM field generator and tracking system, software, a computer system, and a pulmonary pathway reconstruction and planning workstation. The EM tracking accessories that can be used with the SPiN Thoracic Navigation System include Veran's Always-On Tip Tracked™ Guidewire, Sheath, Aspiration Needle, Flexible Needle, Brush, Forceps or View Peripheral Catheter. The SPiN Thoracic Navigation System also enables the placement of markers in soft tissue to guide radiosurgery and thoracic surgery. The SPiN View console/View Optical Probe is provided as an additional accessory for video visualization and is a complement to the EM tracking of the View Peripheral Catheter, enhancing the navigation of the device through the vocal chords and tracheobronchial tree.

5. Indications for Use

The SPiN Thoracic Navigation System is a stereotactic accessory for Computed Tomography (CT) and endoscopic bronchoscope Systems. The SPiN Thoracic Navigation System is indicated for displaying:

- An interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based model of the target organ(s).
- Images of the tracheobronchial tree to aid a physician in guiding endoscopic tools, catheters or guidewires in the pulmonary tract.

The SPiN Thoracic Navigation System compensates for a patient's respiratory phases.

The SPiN Thoracic Navigation System is intended for use in clinical interventions and for anatomical structures where computed tomography and/or endoscopic bronchoscopy are currently used for visualizing such procedures.

The SPiN Thoracic Navigation System enables marker placement within soft lung tissue.

6. Summary of Characteristics to Predicate Device

The SPiN Thoracic Navigation System and the predicate devices have the same intended use, use CT data for creating reference images, have electromagnetic tracking functionality, use instrumentation with sensors for navigation, have similar positioning accuracy, use pulmonary pathway and reconstruction software for planning, reconstruct CT datasets for pathway reconstruction and complete pathway planning through point selection on a 3D model of the tracheobronchial tree for pathway creation. The SPiN Thoracic Navigation System and the SPiN Drive additionally both have an intended use for percutaneous (needle) navigation, auto-detection of reference markers on the CT image and patient, complete a geometry check for tool verification and gate navigation to the effects of respiration. The differences between the SPiN Thoracic Navigation System and the predicate devices include:

- Clarification of the indications for use to include intended use of enabling marker placement within soft lung tissue.
- The update of the SPiN Drive software with a new look/user experience and the ability to run on a Linux computer.

- The introduction of a new electrical cart.
- Addition of the SPiN Perc Biopsy Needle Guide Kit, a convenience kit for percutaneous navigation of instrumentation during a SPiN Perc procedure.
- Addition of the Always-On Tip Tracked 22ga ANSO SPiNFlex Needle and Extended Working Channel (EWC), ethylene oxide sterilized accessories (the EWC has no sensor and is a non-navigated accessory).
- Revision of the Always-On Tip Tracked Steerable Catheter accessory from a reusable accessory to a single-use, ethylene oxide sterilized accessory, with a name of View Peripheral Catheter.
- Change in sterilization methods for the Always-On Tip Tracked Guidewire to ethylene oxide sterilization from gamma radiation.
- Changes in packaging labeling due to the implementation of UDI labeling.
- Incorporation of an additional visualization accessory in the form of the SPiN View console/View Optical Probe.

Risk management, performance testing, and design verification and validation activities have demonstrated that the changes to the SPiN Thoracic Navigation System do not have an effect on the safety and effectiveness of the device as the subject device conforms to all requirements and specifications.

7. Performance Data

Performance data presented to establish substantial equivalence to the predicate devices includes:

- Software verification and validation testing was performed to ensure that the SPiN Drive and SPiN Planning software applications successfully fulfilled the requirements defined in the Software Requirement Specifications (User Requirements) and Software Design Specifications (System Specifications). The verification and validation protocols included detailed descriptions of dependencies, execution instructions, required input, expected output and pass/fail criteria. This testing included demonstrating navigational accuracy on a static phantom. The testing results met the predetermined acceptance criteria that were established in the test protocols. Based on the verification and validation testing, the SPiN Drive and SPiN Planning software applications perform as intended, and it was confirmed that no new questions of safety or effectiveness were identified during testing.
- Electrical safety testing in accordance with AAMI/ANSI/IEC 60601-1 demonstrated that the SPiN Thoracic Navigation System and SPiN View console met all requirements.
- Electromagnetic Compatibility testing in accordance with IEC 60601-1-2 demonstrated that the SPiN Thoracic Navigation System and SPiN View console met all requirements.
- Electrical safety testing for endoscopic equipment in accordance with IEC 60601-2-18 demonstrated that the SPiN View console met all requirements.
- Laser classification was completed for the SPiN View system and it was classified as a Class 3R laser light source. Class 3R lasers are safe if handled correctly with restricted beam viewing. With a class 3R laser, the maximum permissible exposure (MPE) can be exceeded, but with a low risk of injury. Laser classification and hazards analysis has identified appropriate warnings for inclusion in labeling.
- EO sterilization validation was completed for all instrumentation and showed that the instrumentation can be appropriately sterilized to the currently validated ethylene oxide sterilization cycle.
- Biocompatibility testing of EO sterilized instrumentation was completed and demonstrated that no biocompatibility issues exist with the instrumentation.

- Navigational accuracy on a static phantom was completed to demonstrate navigational accuracy of all instrumentation. Functional testing of the instrumentation was completed and demonstrated the durability of the instrumentation.
- Video visualization accessory verification and validation testing, including firmware verification and validation was completed and demonstrated that the video visualization system met all established requirements.
- View Optical Probe accessory functional testing was completed and demonstrated that all established requirements were met.

8. Conclusion

The information presented in the 510(k) submission supports that the SPiN Thoracic Navigation System was shown to be substantially equivalent to the predicate devices in providing electromagnetic navigational bronchoscopy and placing fiducial markers in soft lung tissue. Differences between the SPiN Thoracic Navigation System and the predicate devices do not have an effect on the safety and effectiveness of the SPiN Thoracic Navigation System as demonstrated through the performance data.