K122106

510(k) Summary
Veran Medical Technologies
Traditional 510(k)
SPiN Drive®

DEC 2 1 2012

Date Prepared:

November 21, 2012

510(k) Applicant:

Veran Medical Technologies, Inc.
1908 Innerbelt Business Center Drive
St. Louis, MO 63114
Telephone: (314) 659-8500
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Contact: Scott Wrightstone

Device Information:

Trade Name:	SPiN Drive®
Common Name:	CT stereotactic accessory
Classification Name:	Computed Tomography X-ray System
Classification Code:	JAK

Equivalent Legally-Marketed Device:

ig4™ Endobronchial (K091934)

Device Description:

The SPiN Drive® 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 Drive® 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 Drive® include Veran's Always-On Tip Tracked™ guidewire, steerable catheter, sheath, aspiration needle, brush or forceps.

Intended Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) and endoscopic bronchoscope Systems. The ig4 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 ig4™ System compensates for a patient's respiratory phases.

The ig4™ 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.

Substantial Equivalence:

The SPiN Drive® has been shown to be substantially equivalent to the ig4™ Endobronchial for electromagnetic tracking of endoscopic tools, catheters or guidewires in the pulmonary tract. The SPiN Drive® has been shown to be substantially equivalent to the ig4™ Endobronchial for pulmonary pathway reconstruction and planning. The technological characteristics that have changed from the ig4 Endobronchial to the SPiN Drive include the introduction of an incrementally improved planning workstation (SPiN Planning™) for pulmonary pathway reconstruction and planning and the introduction of additional navigated endoscopic instrumentation (steerable catheter, sheath, aspiration needle, brush and forceps). Dissimilarities between the SPiN Drive® and the predicate device do not affect the safety or effectiveness of the device.

Performance Data:

Bench accuracy testing was completed to demonstrate navigation accuracy on a static phantom. Airway segmentation validation was completed to demonstrate pulmonary planning function equivalence. Functional instrumentation testing was completed on new instrumentation. As required by Veran Medical Technologies design control processes and risk analysis, all verification and validation activities have been completed by designated individuals and have demonstrated the safety and effectiveness of the device.

Clinical Data:

Clinical tests were not required to demonstrate the safety and effectiveness of the device.

Conclusion:

The information provided in the 510(k) notification supports that the SPiN Drive® was shown to be substantially equivalent to the ig4™ Endobronchial for its intended use of navigating endoscopic tools, catheters and guidewires in the pulmonary tract and for pulmonary pathway reconstruction and planning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Mr. Scott Wrightstone
Veran Medical Technologies, Inc.
1908 Innerbelt Bussiness Center Drive
ST. LOUIS MO 63114

Re: K122106
Trade/Device Name: SPiN Drive
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November, 21, 2012
Received: November 26, 2012

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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

K122106

Indications for Use

510(k) Number (if known):

Device Name: SPiN Drive®

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
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