K093995

510(k) Summary JAN 27 2010
Veran Medical Technologies
Traditional 510(k)
ig4™ Image Guided System – Navigation with Ultrasound Overlay
Indications for Use Expansion

Date Prepared:

December 23, 2009

510(k) Applicant:

Veran Medical Technologies, Inc.
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St. Louis, MO 63110
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Contact: Scott Wrightstone

Device Information:

Trade Name: ig4™ Image Guided System
Common Name: CT stereotactic accessory
Classification Name: Computed Tomography X-ray System
Classification Code: JAK

Equivalent Legally Marketed Devices:

ig4™ Image Guided System (K060903)
ig4™ Image Guided System – 3D Fluoroscopic X-ray Navigation (K093146)

Device Description:

The ig4™ Image Guided System is an accessory for a CT or 3D fluoroscopic x-ray System that utilizes electromagnetic tracking technology to locate and navigate instruments relative to a CT-based or 3D fluoroscopic x-ray-based model of the patient anatomy. The system software allows additional data overlay of real-time Ultrasound images onto the model of the patient anatomy. 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 ig4™ System consists of an EM tracking accessory for rigid needles/Ultrasound probes or tip-tracked coaxial needle, a patient referencing system, an EM field generator and tracking system, software and a computer system.

Intended Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) or 3D fluoroscopic x-ray 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 or 3D fluoroscopic x-ray-based model of the target

organ(s). The ig4™ System is additionally indicated for overlaying Ultrasound images onto the model of the target organ(s). The ig4™ System compensates for the patient's respiratory phases.

The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography, 3D fluoroscopic x-ray, or ultrasound are currently used for visualizing such procedures.

Substantial Equivalence:

The ig4™ Image Guided System – Ultrasound Overlay application has been shown to be substantially equivalent in navigating interventional instrumentation as the ig4™ Image Guided System (K060903) navigating instrumentation in CT-based models of the patient anatomy and the ig4™ Image Guided System – 3D Fluoroscopic X-ray (K093146) in navigating instrumentation in 3D Fluoroscopic X-ray-based models of the patient anatomy. This submission demonstrates that the current ig4™ Image Guided System software allows for instrument navigation with images from ultrasound overlay.

Performance Data:

Bench accuracy testing was completed to demonstrate navigation accuracy with Ultrasound overlay on a static phantom. 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 this 510(k) notification supports that the ig4™ Image Guided System – Ultrasound Overlay application was shown to be substantially equivalent to the ig4™ Image Guided System (K060903) and ig4™ Image Guided System – 3D Fluoroscopic X-ray (K093146) in navigating interventional instrumentation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 27 2010

Mr. Scott Wrightstone
QA/RA Manager
Veran Medical Technologies, Inc.
5743 West Park Avenue
ST. LOUIS MO 63110

Re: K093995
Trade/Device Name: ig4™ Image Guided System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 23, 2009
Received: December 28, 2009

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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* Diagnostic Device Evaluation and Safety 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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: ig4™ Image Guided System

Indications for Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) or 3D fluoroscopic x-ray 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 or 3D fluoroscopic x-ray-based model of the target organ(s). The ig4™ System is additionally indicated for overlaying Ultrasound images onto the model of the target organ(s). The ig4™ System compensates for the patient's respiratory phases.

The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography, 3D fluoroscopic x-ray, or ultrasound are currently used for visualizing such procedures.

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

Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K093995