K060903

SECTION 5 – 510(k) Summary

MAY 11 2006

ig4™ Image Guided System

I. Submitter Information

Veran Medical Technologies
2409 21st Avenue South
Suite 205
Nashville, TN 37212
Telephone: (303) 594-3666
Telefax: (615) 297-0911

Contact: Torsten M. Lyon
Date Prepared: March 31, 2006

II. Device Information

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

III. Device Description

The ig4™ Image Guided System is an accessory for a CT System that utilizes electromagnetic tracking technology to locate and navigate instruments relative to a CT-based model of the patient anatomy. Because the system is used to assist in locating 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, a matrix of thoracic reference markers, an EM field generator and tracking system, software, and a computer system.

IV. Intended Use

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) Systems. The ig4 System displays an interventional instrument, such as a biopsy needle, an aspiration needle, or an ablation needle, on a computer monitor that also displays a CT-based model of the target organ(s). The ig4 System compensates for the patient's respiratory phases.

The ig4 System is intended to be used in clinical interventions and for anatomical structures where computed tomography is currently used for visualizing such procedures.

V. Substantial equivalence

The ig4™ Image Guided System was demonstrated to be substantially equivalent to the UltraGuide CT-1010 (K002258), the Medtronic Navigation GoldenEye

System (K001284) and conventional soft tissue navigation with CT images. In addition, bench and animal tests demonstrated that the ig4™ Image Guided System meets the performance requirements for its intended use. Dissimilarities between the ig4™ System and the predicate devices do no affect the safety or effectiveness of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 11 2006

Mr. Torsten M. Lyon
Vice President of Engineering
Veran Medical Technologies, Inc.
2409 21st Avenue South Suite 205
NASHVILLE TN 37212

Re: K060903
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: March 31, 2006
Received: April 3, 2006

Dear Mr. Lyon:

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 (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 – Indications for Use

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510(k) Number (if known): K060903

Device Name: ig4™ Image Guided System

Indications for Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) Systems. The ig4 System displays an interventional instrument, such as a biopsy needle, an aspiration needle, or an ablation needle, on a computer monitor that also displays a CT-based model of the target organ(s). The ig4 System compensates for the patient's respiratory phases.

The ig4 System is intended to be used in clinical interventions and for anatomical structures where computed tomography is currently used for visualizing such procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

David A. Seguran

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060903