MAR 9 2000

K994270

Visualization Technology

What You'd Like to See

510(k) Summary
VISUALIZATION TECHNOLOGY, INC.
INSTATRAK 3000 SYSTEM WITH
FLUOROTRAK MODULE

1. SPONSOR

Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887
Telephone: (978) 933-1000

Primary Contact : Norma LeMay
Sr. Regulatory Affairs Coordinator

Secondary Contact : Peter Ohanian
Vice President, Quality Assurance & Regulatory Affairs

2. DEVICE NAME

Proprietary Name:	InstaTrak 3000 System with FluoroTrak Module
Common/Usual Name:	Interactive Image Guided Surgical System
Classification Name:	Computed Tomography X-Ray System

3. PREDICATE DEVICES

- Visualization Technology Inc., InstaTrak 3000 System, K983529, FDA concurrence received December 31, 1998
- StealthStation System with FluoroNav Module manufactured by Surgical Navigation Technologies, K990214, FDA concurrence received April 22, 1999

4. DEVICE DESCRIPTION

The InstaTrak 3000 System is an image guidance system indicated for use during sinus, skull base, cranial and axial skeletal procedures. The InstaTrak

200 Research Drive
Wilmington, MA 01887
www.vitech.com
Phone: 978.933.1000
Fax: 978.658.5347

3000 with FluoroTrak is similar to the InstaTrak 3000 System cleared under K983529. The changes to the system include software enhancements and the addition of a calibration fixture. Using the InstaTrak 3000, the surgeon can readily identify the immediate location and position of the surgical instrument during the indicated procedure. The InstaTrak 3000 assists the surgeon in avoiding critical nerves and other anatomical structures.

The InstaTrak 3000 offers multiple modes of operation that includes sinus, skull base, cranial, axial skeletal, to the user based on the indications the user desires. Software is available to the user for using any one, two, or all three of the operational modes. A selection of the operational modes is made by the user prior to the procedure depending needs of the user.

The original InstaTrak 3000 System allows the user to view the reconstructed 2D images of the patient's anatomy in response to the mouse or the tracked surgical instrument. Alignment of the patient and images is accomplished through the registration process. In all types of surgery the goal is the same, to indicate to the surgeon based on the pre-operative medical images, where the position of a tracked surgical tool is with regard to the patient's anatomy. The InstaTrak 3000 with FluoroTrak is based on the same hardware and software used in the original InstaTrak System and provides all of the above features. It utilizes the same clinically proven electromagnetic tracking technology as its predecessor.

5. INTENDED USE

The InstaTrak 3000 System is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, long bone, or vertebra, visible on medical images such as CT, MR, or X-ray.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The InstaTrak 3000 with FluoroTrak, the original InstaTrak 3000 and the Stealth Station with FluoroNav are similar in intended use as they are all indicated for locating rigid anatomical structures during either open or percutaneous procedures. The InstaTrak 3000 with FluoroTrak is identical to both the original InstaTrak 3000 System and the Stealth Station with FluoroNav devices in that they are all intraoperative image-guidance systems intended for cranial, skull base, axial skeletal and sinus surgery.

The InstaTrak 3000 with FluoroTrak is essentially identical in technological characteristics to the InstaTrak 3000 System cleared under K983529 with the exception of software enhancements and the addition of the calibration fixture. The InstaTrak 3000 with FluoroTrak uses the same electromagnetic position sensing, and registration process as the original InstaTrak 3000 System cleared under K983529.

The InstaTrak 3000 with FluoroTrak, the original InstaTrak 3000 System and the Stealth Station with FluoroNav all use a computer, monitor and hard disk storage system. Both the FluoroTrak and FluoroNav systems offer image guidance using CT, MR or X-Ray images while the original InstaTrak 3000 System only offers CT and MR images.

There is only one new component associated with the InstaTrak 3000 with FluoroTrak, which is the addition of the calibration fixture. This new component will be used with the InstaTrak 3000 System and has been added to accommodate the FluoroTrak Module .

There are no new instruments used other than what was described in the original 510(k) (K983529) for the InstaTrak 3000 System.

7. PERFORMANCE TESTING

Testing was performed using the new component of the InstaTrak 3000 with FluoroTrak to determine if the new component affected device accuracy. The results showed that the device performed within the specification while using the new component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Norma J. LeMay
Sr. Regulatory Affairs Coordinator
Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887

Re: K994270
InstaTrak 3000 System with FluoroTrak Module
Dated: December 17, 1999
Received: December 20, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA and 90 LLZ

Dear Ms. Lemay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K994370

Device Name: *Visualization Technology, Inc. InstaTrak 3000 with FluoroTrak™ Module*

Indications For Use:

The InstaTrak 3000 System is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, a long bone or vertebra, visible on medical images such as CT, MR, or X-ray.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994370

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)