K983529

DEC 31 1998

510(k) Summary
VISUALIZATION TECHNOLOGY INC
INSTATRAK 3000

1. SPONSOR

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

Contact Person: Peter Ohanian

2. DEVICE NAME

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

3. PREDICATE DEVICES

InstaTrak System, subject of K960330,
Pediatric InstaTrak System, subject of K981998,
Stealth Station manufactured by Surgical Navigation Technologies, subject of K954276
Viewing Wand manufactured by ISG Technologies, Inc., subject of K911783.

4. DEVICE DESCRIPTION

The InstaTrak System is an image guidance system indicated for use during sinus, skull base, cranial and axial skeletal procedures. The InstaTrak 3000 is essentially identical to the InstaTrak System cleared under K960330 and the Pediatric InstaTrak System cleared under K981998 which are both indicated for use during sinus surgery. The changes to the system include a computer upgrade, software enhancements, additional indications and the addition of several components. 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 or 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 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 medical images is accomplished through either an automatic or fiducial registration. The indications for use include sinus cleared under K960330 and pediatric sinus surgery (K981998). 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 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. A newer version of a Sun computer has been substituted to provide 3D display capability which includes 3D models and planar images on top of 3D models, oblique and trajectory matching views. Additionally, a surgical planning capability has been added. This allows the surgeon to plan a trajectory prior to surgery and to observe the pre-surgical track in relation to the actual track during the surgical procedure. A new registration technique has been added whereby the surface of the anatomy can be registered to. New instruments have been added to which tracking sensors have been built in or may be attached. These, along with the surface registration and the new displays allow the system to be used in the proposed indications encompassing axial skeletal, and cranial surgery, in addition to the cleared and pending indications.

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 and axial skeletal visible on medical images such as CT or MR.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The InstaTrak 3000 and the Stealth Station are similar in intended use in that they both are indicated for locating anatomical structures anywhere on the human body in open or percutaneous procedures. The InstaTrak 3000 is identical to both the original InstaTrak System the ISG Technologies Viewing Wand devices in that they are both intraoperative image-guidance systems intended for skull base surgery and sinus surgery.

The InstaTrak 3000 is essentially identical in technological characteristics to the InstaTrak System cleared under K960330 with the exception of computer and software enhancements and some additional components. The InstaTrak System uses the same electromagnetic position sensing, patient headset and automatic headset registration as the original InstaTrak System cleared under K960330.

The InstaTrak 3000, the original InstaTrak System and the ISG Viewing Wand all use a computer, monitor and hard disk storage system. All of the systems offer image guidance using CT or MR scans with the exception of the original InstaTrak System, which only offers CT scans.

There are several new components in the InstaTrak 3000 System. The new components include a nasal specula, mouth gag, pharyngeal retractor, straight extended aspirator, sterile disposable pointer, transmitter, receiver and a head frame. The new components used in the InstaTrak System have been added to accommodate the various applications.

The nasal speculum, mouth gag, and pharyngeal retractor are essentially identical to standard commercial devices and are exempt from the 510(k) premarket notification process. The extended straight aspirator and the disposable pointer are essentially identical to the aspirator and pointer described in the original 510(k) (K960330) for the InstaTrak System.

7. PERFORMANCE TESTING

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 1998

Visualization Technology, Inc.
C/o Mary McNamara-Cullinane
Medical Device Consultants
49 Plain Street
North Attleboro, MA 02760

Re: K983529
Insta Trak 3000
Dated: October 7, 1998
Received: October 8, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 LLZ

Dear Ms. McNamara-Cullinane:

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) 594-4613. 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"(21 CFR 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983529

Device Name: Visualization Technology, Inc. InstaTrak 3000

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983529

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

(Optional Format 1-2-96)