K040050
Page 1 of 3

MAR 2 4 2004

510(k) SUMMARY

GE MEDICAL SYSTEMS NAVIGATION AND VISUALIZATION
INSTATRAK 3500 PLUS WITH MULTIPLE DATASET NAVIGATION

1. SUBMITTED BY:

GE Medical Systems Navigation and Visualization

Primary Contact: Jeff Wagner
GE OEC Medical Systems
384 Wright Brothers Drive
Salt Lake City, UT 84116
Tel (801) 328-9300

2. DEVICE NAME

Proprietary Name:	**InstaTrak with Multiple Dataset Navigation**
Common/Usual Name:	Interactive Image Guided Surgical System
Classification Name:	Image Processing System

3. DEVICE CLASSIFICATION

Image Processing Systems (21 CFR 892.2050 Product Code LLZ) and Computed Tomography Systems (21 CFR 892.1750 Product Code JAK) have been classified under Section 513 of the Act as Class II by the Radiology Devices Panel.

4. PERFORMANCE STANDARDS

No performance standards applicable to this device have been adopted under Section 514 of the Act. The InstaTrak system complies with the following:

CENELEC EN 55011
CENELEC EN 60601-1-2
CENELEC EN 60601-1
UL2601
CSA601

5. DEVICE DESCRIPTION

Intended Use

The InstaTrak 3500 Plus System (K983529, originally cleared under the product name InstaTrak 3000) 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, long bone, or vertebra, visible on medical images such as CT, MR, or X-ray.

General Description

The InstaTrak system with Multiple Dataset Navigation provides the same capability as the existing system, with the additional functionality of utilizing two sets of medical images instead of one. By providing information from multiple datasets, the user can locate and visualize anatomical structures using different imaging modalities.

The InstaTrak 3500 Plus System allows the user to view the medical 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 the registration process. In all types of surgery the goal is the same, to display to the surgeon based on the medical images, where the position of a tracked surgical tool is with regard to the patient's anatomy. With the additional capability of multiple dataset navigation, the surgeon can now view the position of the tracked instrument using two sets of medical images instead of one.

The Multiple Dataset Navigation application will provide the user with the ability to co-register (fuse) images from multiple datasets such as CT and MR. Using the existing InstaTrak 3500 Plus System software, the user will register one of the datasets, referred to as the Reference Dataset, to the patient. Navigation is then possible on the fused images, with secondary (registered) dataset(s) acting as a visualization enhancement for both surgical planning and intra-operative guidance. The sensors and instruments used for navigation are identical to those utilized by the existing InstaTrak system. Navigation will be disabled until the datasets have been successfully co-registered.

Patient registration is the process by which the coordinate systems of the medical images and the pointing instrument are aligned. This is performed on the primary (reference) dataset. Both the method of registration on the primary (reference) dataset and the resulting accuracy are identical to that described in K983529.

The current system provides displays for a single set of medical images. The Multiple Dataset Navigation option will provide displays for multiple sets of medical images.The addition of the Multiple Dataset Navigation operating mode does not change any of the major components of the InstaTrak System. There are no new receivers, transmitters, or instrument attachment configurations associated with this operational mode. Addition of the Multiple Dataset Navigation mode is a software change only.

7. SUBSTANTIAL EQUIVALENCE

The GE Medical Systems Navigation and Visualization Multiple Dataset Navigation option on the InstaTrak system is substantially equivalent to the Image Composer application on the Vectorvision iPlan (K020631), manufactured by BrainLAB, and the StealthStation (K954276) with StealthMerge application, manufactured by Medtronic. Each predicate device also offers the capability to fuse multiple data sets from different imaging modalities. The GE Medical Systems Multiple Dataset Navigation application has the same intended use and utilizes images from the same modalities as the predicate devices. There are no new questions of safety and effectiveness when compared to the predicate devices. The technological platform (InstaTrak, K983529) is unchanged, using the same electromagnetic position sensing and registration process as described in K983529. Except for the Multiple Dataset Navigation function, the InstaTrak system specifications and operating parameters will remain unchanged.

8. CONCLUSION

Based on the above discussion, GE Medical Systems Visualization and Navigation believes that the Multiple Dataset Navigation module is substantially equivalent to the predicate devices.

This concludes this 510(k) summary

Jackie Magno
Vice President, Regulatory and Six Sigma
GE OEC Medical Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

Mr. Jackie Magno
Vice President, Regulatory Affairs
and Six Sigma
GE OEC Medical Systems, Inc.
General Electric Company
384 Write Brothers Drive
SALT LAKE CITY UT 84116-2862

Re: K040050
Trade/Device Name: Insta Trak 3500 Plus with Multiple Dataset Navigation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 22, 2003
Received: January 15, 2004

Dear Mr. Magno:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K040050

Device Name: *GE Medical Systems Visualization and Navigation InstaTrak System with Multiple Dataset Navigation*

Indications For Use:

The 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 anatomical structures such as sinus, skull, 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)

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

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040050