GE Healthcare

NOV 2 3 2005

K051734

510(K) STATEMENT / SUMMARY
AS REQUIRED BY SECTION 807.92(c)

GE HEALTHCARE TECHNOLOGIES
INSTATRAK® 3500 PLUS/FLUOROTRAK™ 9800 PLUS SYSTEM
WITH AXCESS™ BONE PIN

1. SUBMITTED BY:

GE Healthcare Technologies
439 South Union Street, 3rd Floor
Lawrence, MA 01843
Tel (978) 552-5200
Fax (978) 552-5183

2. DEVICE NAME:

GE Healthcare InstaTrak® 3500Plus or FluoroTrak™ 9800 Plus System with Axcess™ Bone Pin

	Systems	Instrument
Proprietary Name	InstaTrak 3500 Plus System OEC FluoroTrak 9800 Plus System	Axcess Cranial Pin*
Common/Usual Name	Interactive Image Guided Surgical System Fluoroscopic Imaging System with Interactive Image Guided Surgical System	Stereotaxic Instrument
Classification Name	Image Processing System Image-intensified Fluoroscopic x-ray System with Image Processing System	Stereotaxic Instrument

Table 1: System and Instrument Names

*Note that the Axcess™ Cranial Pin is one example of the Axcess™ Bone Pin.

3. DEVICE CLASSIFICATION:

Stereotaxic Instrument (21CFR 882.4560 Product Code HAW) has been classified under section 513 of the Act as Class II by the Neurology Devices Panel.

Image Processing System (21CFR 892.2050 Product Code LLZ) has been classified under section 513 of the Act as Class II by the Radiology Devices Panel.

Image-intensified Fluoroscopic x-ray System with Image Processing System (21CFR 892.1650 Product Code 90 JAA and 21CFR 892.1720 Product Code IZL) has been classified under section 513 of the Act as Class II by the Radiology Devices Panel.

4. INTENDED USE / INDICATIONS FOR USE:

The GE Healthcare Navigation and Visualization System (InstaTrak® 3500 Plus System or FluoroTrak™ 9800 Plus System) together with the *Axcess™ Bone Pin*, 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 stereotaxic surgery and which provides a reference to rigid structures such as sinus, skull, long bone or vertebra visible on medical images such as CT, MR or x-ray.

The *Axcess™ Bone Pin* is to be used where rigid fixation of a tracking device to bone is required.

5. SUBSTANIAL EQUIVALENCE:

The GE Healthcare **InstaTrak 3500 Plus System** with Axcess Bone Pin is substantially equivalent to the following:

- LandmarX™ Image Guided Surgical System (K992927) when used with Framelock™ (K022370), the transmitter rigid fixation device - both manufactured by Medtronic Xomed, Inc.
- VectorVision Cranial/ENT (K023651) system, which contains a proprietary transmitter rigid fixation device (Skull Reference Array)- manufactured by BrainLAB AG.

Each predicate device offers a minimally invasive means of direct and rigid fixation to bone. The GE Healthcare InstaTrak 3500 Plus System with Axcess Bone Pin has a similar intended use as the predicate devices. There are no new questions of safety and effectiveness when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 3 2005

GE Healthcare Technologies
c/o Tamas Borsai
Program Manager, Third Party Review Program
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, Connecticut 06470

Re: K051734
Trade/Device Name: GE Healthcare Technologies' InstaTrak® 3500 Plus System or OEAC FluoroTrak™ 9800 Plus with the new Axcess™ Bone Pin
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 7, 2005
Received: November 14, 2005

Dear Mr. Borsai:

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 (240) 276-0115. 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 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,

Barbara Buchinp

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051734

Device Name: GE Healthcare Technologies' InstaTrak® 3500 Plus System or OEC FluoroTrak™ 9800 Plus with the new *Axcess*™ *Bone Pin*

Indications For Use:

The GE Healthcare Navigation and Visualization System [InstaTrak 3500 Plus System (K040050) or OEC FluoroTrak 9800 Plus (K022069)] together with the *Axcess Bone Pin*, 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 stereotaxic surgery and which provides a reference to rigid structures such as sinus, skull, long bone or vertebra visible on medical images such as CT, MR or x-ray.

The *Axcess Bone Pin* is intended to be used where rigid fixation of a tracking device to bone is required.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** ______

(Optional Format 1-2-96)

Barbara Buehrn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051734