NOV 16 1998

K982994

510(k) Summary
for
Visualization Technology, Inc.
Skull Base InstaTrak System

1. Sponsor/Applicant Name, Address

Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887

Contact Person:

Lewis J. Levine
Director of Software Development
Telephone: (978) 933-1000

Date of Summary Preparation:

August 26, 1998

2. Device Name

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

3. Identification of the Predicate or Legally Marketed Device(s) to Which Equivalence Is Being Claimed

InstaTrak System, subject of K960330, the Pediatric InstaTrak System, subject of K981998 and the 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 skull base procedures. The Skull Base InstaTrak System is identical in principles of operation to the InstaTrak System cleared under K960330 and the Pediatric InstaTrak System cleared under K981998, which are indicated for use during nasal surgery. Using the Skull Base InstaTrak System, the surgeon can readily identify the immediate location and position of the surgical instrument during skull base procedures. The Skull Base InstaTrak System assists the surgeon in avoiding critical nerves and other anatomical structures. The Skull Base InstaTrak System includes several new components that were not included in K960330 or K981998, such as a head frame, transmitter arm, extended straight sterile pointer, mouth gag, pharyngeal retractor and nasal speculum. The remainder of the components used in the Skull Base System are identical to those described in the original submission. The additional components do not affect the overall operation of the system as the principles of operation are identical to that described in K960330. Like that system, the Skull Base InstaTrak System is an image guided surgery system that employs a computer with a top mounted swiveling monitor, software and an electromagnetic tracking system. The System uses a Sun SPARC STATION™. The System's proprietary software builds a CT model by taking axial CT images and reconstructing the coronal and sagittal views. The electromagnetic tracking system correlates the movement of surgical instruments to the CT model. The tip of the instrument is displayed as a set of cross hairs in the axial, coronal, and sagittal planes on the InstaTrak System monitor. With the InstaTrak System, CT images are used to assist the surgeon in guiding the position of the instrument during skull base surgery.

The Skull Base and InstaTrak Systems allow pre-operative viewing of the patients' CT images, contextual visualization of the pathology, intra-operative localization, screen display outputs for video recording and positional guidance. The system is operated by acquiring an axial CT scan while the patient wears the InstaTrak System headset and associated instruments. The axial images are then transferred via a network connection or cartridge to the InstaTrak System. The Headset position which stays fixed relative to the patients' anatomy, is automatically identified in the CT images by an image processing algorithm. Coronal and sagittal images are reconstructed and along with the Axial images, provide the CT model that will be used as a road map in surgery.

5. INTENDED USE

The Skull Base InstaTrak System is an image guided device for use during skull base surgical procedures. It is intended to be used during skull Base surgery involving procedures on the base of the brain (junction of the face and neurocranium).

6. A STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO PREDICATE OR LEGALLY MARKETED DEVICE(S) CITED

The Visualization Technology, Inc.'s Skull Base InstaTrak System is substantially equivalent to the Adult InstaTrak System, subject of K960330, and the Viewing Wand manufactured by ISG Technologies, Inc., subject of K911783.

The proposed Skull Base InstaTrak System and the ISG Technologies Viewing Wand devices are both intraoperative image-guidance systems intended for skull base surgery.

The Skull Base InstaTrak System is identical in technological characteristics to the InstaTrak System cleared under K960330. The Skull Base InstaTrak System uses electromagnetic position sensing, patient headset and automatic headset registration as the original InstaTrak.

The Skull Base InstaTrak System, the Adult InstaTrak System and the Viewing Wand all use a computer, monitor and hard disk storage system. The InstaTrak devices use an electromagnetic sensor to determine the location of the pointing instrument being used by the surgeon whereas the predicate ISG device uses a six-jointed, six-degree-of-freedom mechanical articulated arm with an electro-goniometer, which functions as a 3-D digitizer.

Their are several new components in the Skull Base System as described in the Device Description Section of this submission. The new components include a nasal specula, mouth gag, pharyngeal retractor, straight extended aspirator, sterile disposable pointer, transmitter arm and head frame. The new components used in the Skull Base InstaTrak System have been added simply to accommodate the skull base surgical use. The nasal speculum, mouth gag, pharyngeal retractor are exempt from the 510(k) premarket notification process.

7. For 510(k)s Where Determination of Equivalence Is Based on Performance Data

Testing was performed using the new components of the Skull Base InstaTrak 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

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Lewis J. Levine
Director of Software Development
Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887

Re: K982994
Skull Base InstaTrak System
Dated: August 26, 1998
Received: August 27, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 LLZ

Dear Mr. Levine:

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 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,

Lillian Yin, Ph.D.
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): K 98 2994

Device Name: Visualization Technology, Inc. Skull Base InstaTrak System

Indications For Use:

The Skull Based InstaTrak System is intended for image guided assistance during skull base surgical procedures. It is intended to be used during skull base surgery involving procedures on the base of the brain (junction of the face and neurocranium).

(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 K982994

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

(Optional Format 1-2-96)