K981998

AUG 21 1998

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

1. SPONSOR/APPLICANT NAME, ADDRESS

Visualization Technology, Inc.
39G Sixth Road
Woburn, MA 01801

Contact Person:

Robert Murfitt, Ph.D.
Director of Regulatory Affairs and Quality Assurance
Telephone: (781) 938-8920

DATE OF SUMMARY PREPARATION:

June 5, 1998

2. DEVICE NAME

Proprietary Name:	Pediatric 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

Adult InstaTrak System, subject of K960330 and the Viewing Wand manufactured by ISG Technologies, Inc., subject of K911783.

4. DEVICE DESCRIPTION

The InstaTrak System intended for pediatrics is identical to the InstaTrak System intended for adults with the exception of a slight modification to the head set component. The headset assembly, verification pad, and aspirator components have been modified for the Pediatric InstaTrak System. The dimensions of these components of the InstaTrak System have been modified to accommodate the smaller head size of pediatric patients. As described in the original submission, the headset is a single use disposable device made of acetal plastic. The headset is held in place on the patient by spring tension at the three points of contact, the external ear canals, and the bridge of the nose. The headset serves as a foundation for anchoring the electromagnetic transmitter in a fixed location with respect to the patients head to compensate for patient motion during the surgical procedure. The transmitter is attached to the headset prior to surgery by a rotating toggle that is inserted through a slot in the middle of the rectangular section. The headset allows the device to maintain its registration therefore avoiding the need for re-registration during the surgical procedure. It also continues to perform accurately even while the patient's head is moving during the surgical procedure.

The only change between the Pediatric InstaTrak System and the Adult InstaTrak System is a minor change in dimensions of the headset, straight aspirator and verification pad to accommodate the smaller head size of pediatric patients. This is an insignificant modification not affecting safety or effectiveness of the device.

The headset is first worn by the patient during the CT scan and is removed immediately after the scan. Prior to surgery, the transmitter is attached to the headset and the headset is again placed on the patient. This avoids the problem of adhesive based fiducials which requires the CT scan do be done very near the time of surgery to avoid displacement or loss of the markers.

The modifications to the headset dimensions do not affect safety or effectiveness of the device since the intended use and placement are identical to that summarized above and described in more detail in K960330.

5. INTENDED USE

The Pediatric InstaTrak System is an image guided device for use during endoscopic nasal surgery. It is intended to be used during the treatment of acute

and chronic sinusitis, endoscopic dacryocystorhinostomy, optic nerve and orbital decompression, the removal of polyps, the biopsy and removal of tumors, and the repair of CSF leaks, pituitary disorder and encephalocele.

6. A Statement of How the Technological Characteristics of the Device Compare to Predicate or Legally Marketed Device(s) Cited

The Pediatric InstaTrak System is identical in technological characteristics to the Adult InstaTrak System except for the size of the headset. The Pediatric InstaTrak System and the Viewing Wand are similar in that they both use an articulated mechanical arm. The proposed Pediatric InstaTrak System and the predicate devices are similar in intended use in that they are all intraoperative image-guidance systems. The Viewing Wand links a positioning probe to an image display with a patients CT or MRI image data. The Pediatric InstaTrak System, the Adult InstaTrak System and the Viewing Wand all use a computer, monitor and hard disk storage system. Both the pediatric and adult InstaTrak Systems have fewer indications/features, using only CT images and fewer screen image displays than the predicate Viewing Wand. The Viewing Wand does not limit the intended population whereas the Pediatric InstaTrak is intended for pediatric patients only and the Adult InstaTrak is intended for Adult patients only.

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

Pediatric Headset Reproducibility Clinical Testing

Testing was performed to determine the clinical pediatric headset reproducibility on a total of 61 pediatric patients. One large and one small headset was equipped with spherical ear inserts and one large and one small headset was equipped with conical ear inserts. The small headset was to be used for patients with a head circumference $\leq$520 mm and the large for patients with a head circumference $>$520 mm. The testing showed acceptable results for both size headsets with spherical ear inserts only.

Clinical Testing was also performed using the Adult InstaTrak System at four clinical sites. Although this testing was performed on the InstaTrak System intended for adults, it applies to the proposed Pediatric System since the two systems are essentially identical except for minor dimension changes. Results of

this study indicated the mean accuracy of the device to be 2.28 mm with a 95% confidence interval of the mean of 0.78 mm. This compares to values of 1.8 mm to 4.8 mm for the mean accuracy of the ISG Viewing Wand while using various operating modalities and registration techniques. Under these conditions, the 95% confidence interval of the mean for the predicate device varied from 1.1 mm to 1.6 mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1998

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

Re: K981998
Pediatric InstaTrak System
Dated: June 5, 1998
Received: June 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 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): K981998

Device Name: Visualization Technology, Inc. Pediatric InstaTrak System

Indications For Use:

The Pediatric InstaTrak System is intended for image guided assistance during nasal surgery in pediatric patients. It is intended to be used during the treatment of acute and chronic sinusitis, endoscopic dacryocystorhinostomy, optic nerve and orbital decompression, the removal of polyps, the biopsy and removal of tumors, and the repair of CSF leaks, pituitary disorder and encephalocele.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981998

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

(Optional Format 1-2-96)