K960330

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14. SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION IN PREMARKET NOTIFICATION SUBMISSION

General Information

Classification:	Class II 21 CFR 892.1750	Computed Tomography X-ray System
Common Name:		Interactive CT Image-Guided Surgical System
Device Trade Name:		InstaTrak®
Intended Uses:	Anatomical Region:	Intranasal or sinuses
	Diagnoses:	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
Description:		The device consists of a wheeled cabinet enclosure with a 20-inch color monitor mounted on the top. Mounted within the cabinet is a computer and a spacial tracking device. The electromagnetic, six-degree-of-freedom tracking device is linked to the computer, which provides the monitor with a display of the patient's CT image data and superimposed crosshairs, indicating the position of the tip of the surgical instrument used with the device. The device is controlled via software.
Establishment Name and Address:		Visualization Technology, Inc. 656 Beacon Street Boston, MA 02215
Establishment Registration Number:		(Planned)
Performance Standard:		None established under Section 514

Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Safety Parameter Summary

Risk Current:

Enclosure < 100 μA; Patient < 10 μA; ANSI/AAMI ES1-1993

Magnetic Field Intensity:

0.12 Gauss at 4 cm. (14 kHz)

Technological Comparison to Predicate

The InstaTrak device uses an electromagnetic sensor to determine the location of the pointing instrument being used by the surgeon. The predicate device uses a six-jointed, six-degree-of-freedom mechanical articulated arm with an electrogoniometer, which functions as a 3-D digitizer.

The InstaTrak device uses an optional registration mode called autoheadset registration. which makes use of a removable headset that attaches to the patient via the external ear canals and the bridge of the nose. Registration is the process by which the position of the patient is correlated to the CT images. Marked points on the headset that appear on the CT image can be used by a software feature recognition algorithm to automatically locate, in the CT image data, the marked points on the headset. This information, plus the predetermined location of the marked headset points with respect to an electromagnetic transmitter on the headset, allows the entire registration process to be accomplished without the user having to take any action. The predicate device uses either fiducial markers for the registration process or fiducial markers plus unmarked positions on the skin surface of the face.

These technological differences do not effect the safety or effectiveness of the device since the ability of the two devices to accurately determine location is equivalent.

Nonclinical Testing Summary

Laboratory testing was conducted to determine the device accuracy and the performance of the electromagnetic field distortion detection mechanism. Testing was also performed to demonstrate the reproducibility of the location positioning of the replaceable headset and the replaceable pointing instruments.

A mean device accuracy of 0.79 mm was measured which compares to a value of 1.74 mm reported for the predicate device. Results showed that the device detected field distortion under normal use conditions before the induced error became larger than 1.0 mm. The headset was shown to be replaceable such that the overall average effect upon

the device accuracy was less than 0.74 mm. The removal and replacement of a pointing instrument result in a change of less than ±0.914 mm (±3 σ).

Electromagnetic Compatibility testing was conducted and satisfactorily passed. This included emissions in accordance with EN55011(CISPR 11) and RE101 of MIL-STD-461C, and immunity in accordance with IEC 801-2, 801-3, 801-4, 801-5, and RS101 and CS114 of MIL-STD-461C. Because the recommended 10 msec dropout was satisfied, the device has a battery backup.

Clinical Testing Summary

A multicenter study was conducted at four clinical sites. Results of this study indicate 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 predicate device 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.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use. It includes indications for use, cautions, contraindications, warnings, and planning guidance. This information assures safe and effective use of the device.

Substantial Equivalence

The InstaTrak is an image guided surgery device that uses electromagnetic sensing technology and a removable headset to assist during endoscopic surgery through the nasal passages. Its intended use is a subset of those of the Viewing Wand, manufactured by ISG Technologies, Inc. The technology is similar to the Viewing Wand, which uses an articulated mechanical arm and a patient head clamp. The InstaTrak also includes an aspirating function equivalent to the Barnes Suction Tube, a Class I exempt device. The InstaTrak device is substantially equivalent to a combination of these two devices.