K970865

JUN - 4 1997

510(K) SUMMARY

I. COMPANY & CONTACT PERSON

ISG TECHNOLOGIES, INC.
6509 Airport Road
Mississauga L4v-1S7
Ontario, Canada

II. DEVICE NAME AND CLASSIFICATION

Family of Viewing Wands

Classification: Stereotatic Instrument (21 CFR 882.4560)

III. DESCRIPTION OF DEVICE

The ISG Family of Viewing Wands is comprised of a medical imaging workstation that is integrated with a position-sensing user directed probe. This allows for the provision of information pertaining to the current position of the probe related to the surrounding anatomy by correlating pre-operative CT and/or MR imaging data with the intraoperative situation. Once a patient's CT or MR images have been transferred to the workstation, the patient is correlated to that image dataset. The system then displays the orientation of the probe and the position of the tip on the corresponding image, updating the display in real-time as the probe is moved.

IV. INTENDED USE

The Family of Viewing Wands, (including cranial and spinal applications) is comprised of a medical workstation and an integrated position sensing probe, is intended to be used pre-operatively and intra-operatively.

V. SUBSTANTIAL EQUIVALENCE

The spinal application as described in this submission is a line (application) extension to the Family of Viewing Wands (K960714) and is substantially equivalent to other devices (Stealth Station - K954276) within the classification of diagnostic devices (21CFR 882.4560) that have been reviewed under the provisions of the Medical Device Amendments and are being marketed in interstate commerce.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 1997

Mr. Charles Hall
Director, Clinical Development
ISG Technologies, Inc.
6509 Airport Road
Mississauga, Ontario
CANADA L4V 1S7

Re: K970865
Trade Name: ISG Family of Viewing Wands
Regulatory Class: II
Product Code: 84HAW
Dated: March 4, 1997
Received: March 10, 1997

Dear Mr. Hall:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K970865

Device Name: ISG Family of Viewing Wands

Indications For Use:

The Family of Viewing Wands, (including cranial and spinal applications) is comprised of a medical workstation and an integrated position sensing probe, is intended to be used pre-operatively and intra-operatively to perform the following functions:

- process and display pre-operatively radiographic images on a monitor;
- provide intra-operative image information based on the position and orientation of a user directed probe;
- allow for the optical integration and usage of different position sensing technologies (e.g. articulated arm, infrared freehand) and surgical probes (handheld pointers);
- store/retrieve image data on computer access media (e.g. hard disks, archive media); and
- transmit data over local area and wide area networks.

Circumstances:

The Family of Viewing Wands is intended to be used pre-operatively:

- when more than one approach (e.g. entry point, trajectory, craniotomy size, screw placement) is being considered;
- when determining the size of any instrumentation;

continued...

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970865

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

...Circumstances, continued:

and intra-operatively, when:

- the target, trajectory, or approach is in a region with few anatomical landmarks (e.g. subcortical brain) or with complex anatomy (e.g. scoliosis, fractures, deformity);
- the target, trajectory, or approach is not entirely exposed (e.g. posterior approach for screw placement);
- the target, trajectory, or approach is in a region where the normal landmarks have been distorted either by disease (e.g. degenerative disease, osteophytes) or by previous surgery;
- the target, trajectory, or approach is in close proximity to critical structures (e.g. venous sinuses, air sinuses, spinal nerve roots or blood vessels) which must be avoided or negotiated; or
- the target's delineation is important and will not move significantly during the approach (e.g. skull based tumors, sinus diseases, corpus callosotomies, spinal cord tumors).

Disease or Conditions:

The Family of Viewing Wands is indicated for patients who have space-occupying lesions or malformations (both soft tissue and osseous) in the head.

It is also indicated for patients who require decompressive or reconstructive surgery of the spine, or who have imaged space-occupying lesions or malformations in the spine.

The Family of Viewing Wands is contraindicated for patients suspected of having Creutzfeld-Jakob's disease if adequate sterilization of the instrument cannot be assured.