JAN 1 3 1999

K982570

510(k) Summary of Safety and Effectiveness

Submitter:	I.S.G. Technologies Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa, Clinical Scientist
Telephone:	(905) 672-2100
Date:	July 17, 1998
Trade Name:	SNN Scout.
Common Name:	Image-Guided Surgical System.
Classification Name:	Accessory to Stereotaxic Device.
Predicate Device:	ISG Family of Viewing Wands.
Device Description:	The passive sensor feature is an addition to the SNN Scout image-guided surgical system. This feature is designed to improve the ergonomics of the user/device interaction by eliminating the cable connections between the tracked surgical instruments and the computer workstation.
Intended Use:	The SNN Scout, comprised of a medical workstation and an integrated position-sensing instrument, is intended to be used pre-operatively and intra-operatively.
Comparison to Predicate:	The intended use and technological characteristics of the SNN Scout image-guided surgical device including the passive sensor feature are substantially equivalent, in the opinion of I.S.G. Technologies, to those of the predicate device and do not pose any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1999

Ms. Carol Nakagawa
Clinical Scientist
ISG Technologies, Inc.
6509 Airport Road
Mississauga, Ontario
Canada L4V 1S7

Re: K982570
Trade Name: SNN Scout
Regulatory Class: II
Product Code: HAW
Dated: November 5, 1998
Received: November 9, 1998

Dear Ms. Nakagawa:

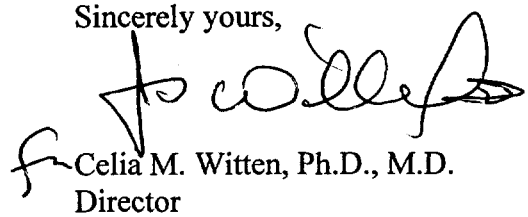
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. Indications for Use

The passive instrument feature does not change the indications for use of the SNN Scout image-guided surgical device compared with the predicate ISG Family of Viewing Wands. The statement of indications for use continues to be as follows:

> "The SNN Scout 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 of the spine. The SNN Scout is contraindicated for patients suspected of having Creutzfeld-Jacob's disease if adequate sterilization of the instruments cannot be assured."

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982570