K993673

DEC 21 1999

510(k) Summary of Safety and Effectiveness

Submitter:	Surgical Navigation Specialists Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Dolores McGirr, Regulatory Scientist
Telephone:	(905) 672-2100
Date:	October 26, 1999
Trade Name:	SNN Fluoro Navigation System
Common Name:	Image-Guided Surgical System.
Classification Name:	Stereotaxic Device.
Predicate Devices:	SNN System K982570; the Stealth Station with FluoroNav Module by Surgical Navigation Technologies K990214.
Device Description:	The SNN Fluoro Navigation System is a module of the SNN System to provide image-guided surgery based on an intra-operative fluoroscopic image of the patient anatomy.
Intended Use:	The SNN Fluoro Navigation System, comprised of a medical workstation and an integrated position-sensing instrument, is intended to be used intra-operatively for localization and navigation.
Comparison to Predicates:	The intended use and technological characteristics of the SNN Fluoro Navigation system are substantially equivalent, in the opinion of SNS Inc., to those of the predicate devices 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

DEC 21 1999

Mrs. Dolores McGirr
Regulatory Scientist
Quality Engineering Support Team
I.S.G. Technologies, Inc.
6509 Airport Road
Mississauga, Ontario
Canada L4V 1S7

Re: K993673
Trade Name: SNN Fluoro Navigation System
Regulatory Class: II
Product Code: HAW
Dated: October 26, 1999
Received: November 1, 1999

Dear Mrs. McGirr:

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,

for Stephen Rhodes

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 993673

Device Name: The SNN Fluoro Navigation System

Indications For Use :

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

The SNN Fluoro Navigation Module is also indicated for situations where reference to a rigid anatomical structure such as the skull, a long bone or vertebra can be identified relative to a fluoroscopic image of the anatomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993673