AUG 27 1999

510(k) Summary of Safety and Effectiveness

K992457

Submitter:	Surgical Navigation Specialists Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa.
Telephone:	(905) 672-2100.
Date:	July 21, 1999.
Trade Name:	SNN image-guided surgical system with optional Olivier Double-Chuck Support Arm.
Common Name:	Image-Guided Surgical System.
Classification Name:	Accessory to Stereotaxic Device.
Predicate Devices:	The SNN image-guided surgical system, the Philips EasyTaxis option to the EasyGuide system, and the Radionics Optical Tracking System with the frameless cranial biopsy indication.
Device Description:	The Olivier Double-Chuck Support Arm is an optional component of the SNN image-guided surgical system. The arm itself can be positioned and locked into place. The double-chuck head has one chuck to firmly hold a surgical instrument in the desired location. The instrument can also be moved up or down by sliding it through the chuck. The second chuck is used to prevent excessive vertical movement, by stabilizing the arm against the skull.
Intended Use:	The SNN image-guided surgical system (including cranial and spinal applications), comprised of a medical workstation and an integrated position sensing instrument and the Olivier Double-Chuck Support Arm option, is intended to be used pre-operatively and intra-operatively for various planning, localization, and navigation purposes.
Comparison to Predicate:	The intended use and technological characteristics of the SNN image-guided surgical device including the Olivier Double-Chuck Support Arm option, are substantially equivalent, in the opinion of Surgical Navigation Specialists 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

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Surgical Navigation Specialists, Inc.
c/o Ms. Carol Nakagawa
Clinical Scientist
Department of Clinical Development
I.S.G. Technologies, Inc.
6509 Airport Road
Mississauga, Ontario
Canada
L4V 1S7

Re: K992457
Trade Name: The SNN System with the Olivier Double-Chuck Support Arm Option
Regulatory Class: II
Product Code: HAW
Dated: July 21, 1999
Received: July 23, 1999

Dear Ms. Nakagawa:

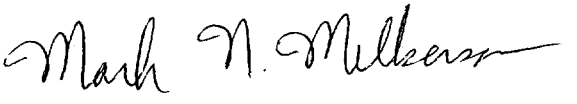
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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 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

510(k) Number (if known): K992457

Device Name: The SNN System with the Olivier Double-Chuck Support Arm Option

Indications For Use:

The SNN system with the Olivier Double-Chuck Support Arm Option 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 Olivier Double-Chuck Support Arm Option can provide mechanical support and guidance for various frameless stereotaxic procedures, tumor resections, biopsies, and endoscopies.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhersen

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992457

(Optional Format 3-10-98)