510(k) Summary of Safety and Effectiveness

K994421

Submitter:	Surgical Navigation Specialists Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa.
Telephone:	(905) 672-2100.
Date:	February 18, 2000.
Trade Names:	SNN Stereotactic Planning Application; SNN Stereotactic Application.
Common Name:	Stereotactic Head Frame software accessory.
Classification Name:	Accessory to Stereotaxic Instrument.
Predicate Devices:	StereoPlan and AtlasPlan software from Radionics, and @Target software from Brainlab.
Device Description:	The SNN Stereotactic Planning Application software is an optional module of the SNN System software. The SNN Stereotactic Planning Application module registers medical scan images with stereotactic frame space and calculates frame and arc system coordinates.
Intended Use:	The SNN Stereotactic Planning Application module is intended to be used as an accessory for planning stereotactic frame-based procedures such as biopsies, functional stereotaxy, tumor resections, vascular malformation surgeries, thalamotomies and pallidotomies.
Comparison to Predicate:	The intended use and technological characteristics of the SNN image-guided surgical device including the SNN Stereotactic Planning Application software module is 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

FEB 23 2000

Surgical Navigation Specialists, Inc.
c/o Ms. Carol Nakagawa
Regulatory Scientist
Cedara Software Corporation
6509 Airport Road
Mississauga, Ontario
Canada L4V 1S7 T

Re: K994421
Trade Name: SNN Stereotaxic Planning Application
Regulatory Class: II
Product Code: HAW
Dated: December 28, 1999
Received: December 29, 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 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 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): K994421

Device Name: SNN Stereotactic Planning Application

Indications For Use :

The SNN Stereotactic Planning Application module is intended to be used as an accessory for planning stereotactic frame-based procedures such as biopsies, functional stereotaxy, tumor resections, vascular malformation surgeries, thalamotomies and pallidotomies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994421