K971247

JUN 16 1997

510(k) Summary of Safety and Effectiveness

SNT DISPOSABLE BIOPSY NEEDLE

I. **Company:** Surgical Navigation Technologies, Inc.
530 Compton Street
Broomfield, CO 80020

II. **Product Name:** SNT DISPOSABLE BIOPSY NEEDLE

III. The SNT DISPOSABLE BIOPSY NEEDLE is intended to be used for stereotaxic biopsy of brain tissue. This needle is only intended for use with the StealthStation™ Image Guided Surgery System and it's rigid needle guide holder.

IV. The SNT DISPOSABLE BIOPSY NEEDLE was claimed to be substantially equivalent to the stereotatic biopsy needle manufactured by RADIONICS and used in their Nashold Biopsy Needle Kit. The only difference is that their device uses stereotactic coordinates that are dialed into a guide holder on a headframe to lead the needle while our device is tracked using an LED that is tracked by the STEALTHSTATION™. In addition, the SNT DISPOSABLE BIOPSY NEEDLE was claimed to be substantially equivalent to several commercially available biopsy needles. A comparison of these needles was supplied in support of establishing equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1997

Mr. David A. Mire
Clinical and Regulatory Affairs Associate
Surgical Navigation Technologies, Inc.
530 Compton Street
Broomfield, Colorado 80020

Re: K971247
Trade Name: SNT Disposable Biopsy Needle
Regulatory Class: II
Product Code: 84HAW
Dated: March 14, 1997
Received: April 3, 1997

Dear Mr. Mire:

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

CONFIDENTIAL

510(k) Number (if known): ____

Device Name: SNT Disposable Biopsy Needle

Indications For Use:

The SNT DISPOSABLE BIOPSY NEEDLE is intended to be used for stereotaxic biopsy of brain tissue. This needle is only intended for use with the StealthStation™ Image Guided Surgery System and it's rigid needle guide holder. The biopsy needle is supplied sterile and is intended for single use only.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K971247

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)