K971893

Summary of Safety and Effectiveness

SNT Linac Accessories

NOV 13 1997

I. Company: Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709

II. Product Name: SNT Linac Accessories

III. The SNT Linac Accessories are indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial lesions. The accessories include a secondary collimation system, components to mount a patient in a stereotactic headring to a linear accelerator's treatment couch, and components to position the patient relative to the isocenter of a linear accelerator in conjuction with a laser alignment system.

IV. The SNT Linac Accessories were shown to be substantially equivalent to other commercially available linear accelerator accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

Roger N. White
Group Director, Regulatory Affairs
Surgical Navigation Technologies, Inc.
530 Compton Street
Broomfield, CO 80020

Re: K971893
SNT Linac Accessories
Dated: August 15, 1997
Received: August 18, 1997
Regulatory class: II
21 CFR 892.5050 /Procode: 90 IYE

Dear Mr. White:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971893

Device Name: SNT Linac Accessories

Indications For Use:

The SNT Linac Accessories are indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial lesions. The accessories include a secondary collimation system, components to mount a patient in a stereotactic headring to a linear accelerator's treatment couch, and components to position the patient relative to the isocenter of a linear accelerator in conjuction with a laser alignment system.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

David A. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971893

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)