DEC 4 1998

K983397

510(k) Summary

StealthStation™ System Sterilization Change

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

II. **Product Name:** StealthStation™ System

III. This submission describes updates made to the StealthStation™ System to provide the option for sterilizing instruments using an additional steam autoclave cycle.

IV. The indications for use for the StealthStation™ System have not changed and are as follows:

> The StealthStation™ System is intended as an aid for precisely locating anatomical locations in either open or percutaneous procedures. The StealthStation™ System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy. The StealthStation™ System with the ENT option is also indicated for intranasal or sinus use.

V. StealthStation™ System Sterilization Change was shown to be substantially equivalent to the StealthStation™ System that was previously cleared. Validation information was provided to support the change.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Mr. Roger N. White
Group Director
Quality Systems and Regulatory Affairs
Surgical Navigation Technologies, Inc.
530 Compton Street
Broomfield, Colorado 80020

Re: K983397
Trade Name: StealthStation™ System
Regulatory Class: II
Product Code: HAW
Dated: September 24, 1998
Received: September 25, 1998

Dear Mr. White:

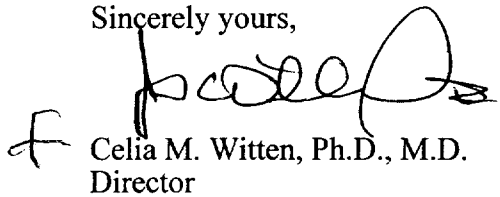
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



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): K983397

Device Name: StealthStation® System

Indications For Use:

The StealthStation™ System is intended as an aid for precisely locating anatomical locations in either open or percutaneous procedures. The StealthStation™ System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy. The StealthStation™ System with the ENT option is also indicated for intranasal or sinus use.

(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 General Restorative Devices
510(k) Number K983397

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)