

JAN 12 1999

510(k) Summary

StealthSERVER™ Image Storage and Communication System

- I. **Company:** Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709
- II. **Product Name:** StealthSERVER™ Image Storage and Communication System
- III. This submission describes a network server system that provides remote access to digital image sets for the purpose of reviewing the images and, optionally, for developing and storing a stereotactic surgical plan that is compatible with the StealthStation® Image Guided Treatment Platform. The submission includes the capability of the StealthStation® System to retrieve the surgical plans and image sets from the network server.
- IV. The StealthSERVER™ Image Storage and Communication System was shown to be substantially equivalent to other commercially available medical image storage, review and communication systems.



JAN 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Roger N. White
Group Director, Regulatory Affairs
Surgical Navigation Technologies, Inc.
530 Compton Street
Broomfield, CO 80020Re: K984000
StealthSERVER
Dated: November 6, 1998
Received: November 10, 1998
Regulatory class: I
21 CFR 892.2020/Procode: 90 LMD

Dear Mr. White:

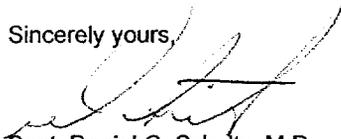
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting 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): K984000

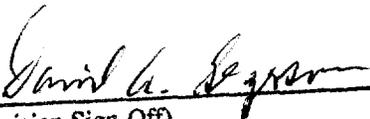
Device Name: StealthSERVER™ Image Storage and Communication System

Indications For Use:

The StealthSERVER™ Image Storage and Communication System is used to store and provide remote viewing access to diagnostic images via a LAN, the internet or modem. In addition, the system can be used to remotely set surgical plans for stereotactic surgery that are compatible with and can be accessed by the StealthStation® Treatment Guidance Platform.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984000

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)