K992354

OCT 12 1999

Image Analysis System
510(k) Summary

Date Prepared: July 13, 1999

I. Submitter Information:

Contact: Roger N. White
Group Director, Quality Systems and Regulatory Affairs
Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709
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II. Trade name: Image Analysis System
Common or usual name: Image Processing System
Classification name: Image Processing System (per 21 CFR section 892.2050)

III. The above device is substantially equivalent to the MR Workstations manufactured by Picker International, Inc. (K961637) and the AccuImage Image Display Processor manufactured by AccuImage, Inc. (K961023). The substantial equivalence was established by comparison of functions and features.

IV. This submission describes a system to display, transfer, store, analyze and process patient image sets. The processing of image data includes the ability to segment anatomical structures.

V. The Image Analysis System is intended to provide a method of storing and providing remote viewing and analyzing access to diagnostic images via a LAN, the internet, or a modem. The system is also intended to provide the display of segmented anatomical structures based on the correlation of the image sets to atlas information. Examples of structures that may be segmented include but are not limited to: vertebral bodies, prostate, hippocampus, and the basal ganglia.

VI. The technological characteristics are the same as or similar to those found with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 1999

Roger N. White
Group Director
Quality Assurance and Regulatory Affairs
Surgical Navigation Technologies, Inc.
530 Compton St.
Broomfield, CO 80020

Re: K992354
SNT Image Analysis System
Dated: July 13, 1999
Received: July 14, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

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): K992354

Device Name: Image Analysis System

Indications For Use:

The Image Analysis System is intended to provide a method of storing and providing remote viewing and analyzing access to diagnostic images via a LAN, the internet, or a modem. The system is also intended to provide the display of segmented anatomical structures based on the correlation of the image sets to atlas information. Examples of structures that may be segmented include but are not limited to: vertebral bodies, prostate, hippocampus, and the basal ganglia.

(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 K992354

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

(Optional Format 1-2-96)