K082354

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510(k) SUMMARY

As required by section 807.92(c)

Naviscan, Inc.'s Stereotactic Navigation Accessory

Stereo Navigator Accessory for the PEM Flex® PET Scanner

Company Name:	**Naviscan, Inc.**
Address:	11180 Roselle Street, Suite 100
	San Diego, CA 92121
Contact Person:	Heather Jalisi
Phone:	858.332.0942
Fax:	858.857.2596
Date Prepared:	August 12, 2008
Trade name:	Stereo Navigator Accessory for the PEM Flex® PET Scanner
Classification Name:	Accessory to Emission Computed Tomography System
	21 CFR 892.1200, Product Code 90-KPS, Device Class II
Predicate Devices:	Stereotactic Localization Device (SLD), *Philips Medical Systems*
	Confirma Breast MRI Interventional Components, *Confirma, Inc.*
	SureLoc® CADstream 4.0 System, *Confirma, Inc.*

510(k) Summary, Stereo Navigator Accessory

Intended Use / Indications for Use:

The Stereo Navigator Accessory is an optional accessory to the PEM Flex® PET Scanner. It is intended for the localization of lesions in female breasts, as identified on a PET image. By using the Stereo Navigator, the physician is able to guide compatible interventional devices towards the PET abnormality as medically indicated. The Stereo Navigator also provides a means to confirm localization of the lesion in advance of the interventional procedure.

Technological Characteristics:

The Stereo Navigator determines the three dimensional coordinates of a user-defined target for an imaged abnormality (e.g. lesion) displayed on the PEM Flex PET Scanner. Since PEM Flex tomographic images are displayed as a series of 2D planar slices, the user must define a target on two orthogonal images to define all three axis coordinates of the target location. These coordinates are processed into stereotactic information by the Stereo Navigator software which is used by the healthcare provider to position a stereotactic frame for guiding the trajectory of an interventional device and for determining the depth to which the interventional device should be inserted along the trajectory.

Additionally, the Stereo Navigator provides a means for the user to confirm that localization has been achieved during the interventional procedure and prior to sampling or marking. This is accomplished by placing an encapsulated positron-emitting line source (radioactive line source) through the tissue access port (cannula) of the interventional device to the intended sampling or marking site,

acquiring an image and comparing the location of the line source relative to the lesion (in at least two orthogonal image planes).

Performance Data:

The Stereo Navigator was subject to preclinical (phantom) studies and confirmatory clinical studies. These studies demonstrated that the device is substantially equivalent to the predicates with respect to safety and effectiveness.

Substantial Equivalence:

The Stereo Navigator is as safe and effective as the 1) Stereotactic Localization Device (SLD), 2) Confirma Breast MRI Interventional Components, and 3) SureLoc® CADstream 4.0 System, ("Predicate Devices"). The Stereo Navigator has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Stereo Navigator and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Stereo Navigator is as safe and effective as the Predicate Devices. Thus, the Stereo Navigator is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Heather Jalisi
Director, Quality and Regulatory
Naviscan, Inc.
11180 Roselle Street, Suite 100
SAN DIEGO CA 92121

Re: K082354
Trade/Device Name: Stereo Navigator Accessory for the PEM Flex® PET Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 12, 2008
Received: August 26, 2008

Dear Ms. Jalisi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082354

Device Name: Stereo Navigator Accessory for the PEM Flex® PET Scanner

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 and Radiological Devices
510(k) Number K082354