K090553

MAR 3 1 2009

510(k) Premarket Notification
Naviscan, Inc.
PEMFlex Solo II High Resolution PET Scanner
510(k) Summary

Submission Date:	27 February 2009
Submitter:	Naviscan, Inc. 6865 Flanders Drive, Suite B San Diego, CA 92121 USA
Submitter Contact:	Ms. Heather Jalisi Director, Quality and Regulatory Affairs 858 332 9042 hjalisi@naviscan.com
Manufacturing Site:	Naviscan, Inc. 6865 Flanders Drive, Suite B San Diego, CA 92121 USA
Trade Name:	Naviscan, Inc. PEMFlex Solo II High Resolution PET Scanner
Common Name:	Positron Emission Tomography System
Classification Name:	System, Tomography, Computed, Emission
Classification Regulation:	21 CFR §892.1200
Product Code:	KPS

Substantially Equivalent Devices:

New Naviscan Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
PEMFlex Solo II High Resolution PET Scanner	K032063	Naviscan, Inc. PEM 2400 PET Scanner

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Device Description: The Naviscan, Inc. (Naviscan) PEMFlex Solo II High Resolution PET Scanner (Solo II) is a high spatial resolution, small field-of-view PET imaging system specifically developed for close-range, spot, i.e. limited field, imaging. The Solo II is a partial-ring PET scanner, equipped with lutetium-containing gamma-ray detectors, which collects gamma rays emitted by injected positron-emitting radiopharmaceuticals, and generates images corresponding to concentration of these radiopharmaceuticals in the body. The Solo II is designed to collect gamma rays from a patient's body part with high efficiency. In order to achieve this high efficiency, the detectors should be positioned as close as possible to the body part under examination. Properly configured, the Solo II can display images obtained from other digital imaging modalities for correlative purposes.

Intended Use: The Naviscan, Inc. PEMFlex Solo II High Resolution PET Scanner is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body.

Technology Comparison: The Solo II employs the same technological characteristics as the predicate devices to collect and generate radiological images. This consists of lutetium-containing gamma-ray detectors that collect gamma rays emitted by injected positron-emitting radiopharmaceuticals, and generates images corresponding to concentration of these radiopharmaceuticals in the body.

Summary of Performance Testing:

Biocompatibility The patient contact material in the Solo II was tested for biocompatibility in accordance with applicable Standards.

Test results indicated that the patient contact material in the Solo II complies with its predetermined specification and with the applicable Standards.

Electrical Safety The Solo II was tested for patient safety in accordance with applicable Standards.

Test results indicated that the Solo II complies with its predetermined specification and with the applicable Standards.

Electromagnetic Compatibility Testing	The Solo II was tested for EMC in accordance with applicable Standards. Test results indicated that the Solo II complies with its predetermined specification and with the applicable Standards.
Performance Testing	The Solo II was tested for performance in accordance with applicable Standards. Test results indicated that the Solo II complies with its predetermined specification and with the applicable Standards.
Software Testing	Software for the Solo II was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Solo II complies with its predetermined specification.
Clinical Images	Three (3) clinical case images are provided from the Solo II to demonstrate the high resolution image capability of the Solo II. Image results indicated that the Solo II complies with its predetermined specification.
Conclusion	Based upon a comparison of devices and performance testing results, Solo II is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2009

Ms. Heather Jalisi
Director, Quality and Regulatory Affairs
Naviscan, Inc.
6865 Flanders Drive, Suite B
SAN DIEGO CA 92121

Re: K090553
Trade/Device Name: Naviscan PEMFlex Solo II High Resolution PET Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 27, 2009
Received: March 2, 2009

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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 090553

Device Name: Naviscan PEMFlex Solo II High Resolution PET Scanner

Indications for Use: The Naviscan PEMFlex Solo II High Resolution PET Scanner is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K090553