SEP - 1 2006

K062393

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: GE Vantage PET Neuro Software
Date prepared: May 26, 2006

Establishment Name and Registration Number of Submitter

Name: GE Healthcare (Formerly GE Medical Systems)
Registration Number: 2126677
Corresponding Official:

D. Duersteler
GE Healthcare
P.O. Box 414
Milwaukee, WI 53201
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Device Classification

Classification Code: 90 KPS
Panel Identification: Radiology
Classification Name: Emission Computed Tomography System (Per 21CFR 892.1200)
Common Name: PET/CT Imaging Software
Classification Class: Class II Product
Reason for 510(k) Submission: New device

Device Description

The Vantage package includes automated analysis and review of PET and PET-CT brain scans. It has been developed to aid in assessment of human brain scans through quantification of the comparison of local peak activity values at standardized anatomical locations with the corresponding reference normal peak activity in age stratified normal database (or asymptomatic control subjects as defined). It provides a basic review of any PET brain scan, realignment of the PET volume to a standard atlas and comparison to brain scans derived from control subjects or prior PET and/or MR scans. Results are displayed in user-friendly graphical format as Z-score, where Z-score is the scale of the deviation from the normal mean, relative to corresponding standard deviation.

Identification of Legally Marketed Equivalent Devices

NeuroQ	Syntermed, Inc.		K041022
Scenium	Mirada Solutions, Ltd.	K042863	

Comparison with Predicate Devices

Vantage as compared with the above predicate devices provides a clinically focused software solution for brain analysis with PET and PET/CT imaging. Similar to Scenium and Neuro Q, Vantage™ is a post processing tool that assists in regional assessment of human brain scans by providing comparison between a patient brain scan to a brain scan derived from FDG-PET studies of a defined group of control subjects, where the asymptomatic control group is as defined and age stratified by a neurologist with medical expertise. The algorithms used in Vantage™ to calculate quantitative measures compares local peak activity values instead of average peak activity values used by predicate devices; at standardized anatomical locations with the corresponding reference normal peak activity in age stratified control subjects.

Indications for Use of Device

The GE Vantage PET Neuro Software has been developed to aid clinicians in the assessment and quantification of pathologies derived from PET and PET-CT brain scans. The software is deployed via Advantage Windows Workstation and PET-CT scanner console and is organized as a series of workflows steps, which are specific to use with particular drug and disease combination.
The software aids in the assessment of human brain scans enabling automated analysis through quantification of the comparison of local peak activity values at standardized anatomical locations with the corresponding reference normal peak activity in age stratified control subjects. The resulting quantification is presented to the user through 3D stereotactic surface projection maps of the brain. The package allows the user to generate information regarding relative changes in PET-FDG metabolic activity between a subjects images and age stratified controls, which may be resulting from brain function alterations by neurodegenerative processes.
CT fusion to PET offers visualization of structural abnormalities, which may result from brain injury, trauma, disorder, disease or dysfunction, such as subdural hematoma, tumor, stroke (or cerebrovascular disease) etc. Such tools may aid the physician in the rule out process.

Conclusion

In the opinion of General Electric Medical Systems, the GE Vantage PET Neuro Software is substantially the same in design, materials, energy sources, and technology, does not introduce new safety concerns, performs as well as currently marketed devices, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed Syntermed NeuroQ (K041022) and Mirada Solutions Scenium (K042863) products.

General Electric Company
P.O. Box 414
Milwaukee, WI 53201

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 1 2006

GE Healthcare
% Mr. Tamas Borsai
Responsible Third Party Official
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K062393
Trade/Device Name: Vantage
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 11, 2006
Received: August 16, 2006

Dear Mr. Borsai:

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 (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 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). 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K062393
Device Name: Vantage
Indications for Use:

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The software aids in the assessment of human brain scans enabling automated analysis through quantification of the comparison of local peak activity values at standardized anatomical locations with the corresponding reference normal peak activity in age stratified control subjects. The resulting quantification is presented to the user through 3D stereotactic surface projection maps of the brain. The package allows the user to generate information regarding relative changes in PET-FDG metabolic activity between a subjects images and age stratified controls, which may be resulting from brain function alterations by neurodegenerative processes.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062393