K111161

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K_____

I. Applicant Information

Applicant:

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France

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Application Correspondent:

EMERGO GROUP INC.
611 West 5th Street, Third Floor
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U.S.A.

Contact Person: Kristi Gusman
Project Manager
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Date Prepared: April 15, 2011

II. Device Name and Classification

Proprietary Name:	PERFSCAPE V2.0
Common/Usual Name:	PACS
Classification Name:	Picture Archiving Communications System
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Device

The PERFSCAPE V2.0 device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K090546
Trade Name:	Nordic Image Control and Evaluation (nICE) Software
Manufacturer:	NordicIceMedical AS
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II

IV. Device Description

PERFSCAPE V2.0 is a software application designed to analyze dynamically acquired datasets. The software provides a wide range of basic image processing and manipulation functions applied to MRI or CT datasets.

Using well-established algorithms, parametric maps can be generated such as Relative Blood Volume, Relative Blood Flow, Relative Mean Transit Time, Time to Peak, impulse response time to peak, permeability and leakage between intravascular and extracellular space (MRI only), temporal Maximum Intensity Projection (CT only). PERFSCAPE V2.0 also generates Diffusion Weighted Images and/or Diffusion Tensor Images (DWI and DTI, MRI only).

The PERFSCAPE V2.0 device includes critical features such as:

- Enables the computation of DWI and DTI maps from co-registered Bxxx images (eg B0 B500 B1000);
- Enables rapid creation of a complete array of critical parameter maps;
- Automated organ mask generation;
- View dynamic signal time course on a per-voxel basis;
- Integrated motion correction ;
- Automatic and Interactive Arterial Input Function (AIF) selection;
- Automatic and Interactive Venous Output Function (VOF) selection;

- Export computed perfusion map to PACS or to DICOM files in filesystem.

PERFSCAPE V2.0 also allows the user to view the computed maps using the NEUROSCAPE software (K083491).

Based on these common functionalities, Perfscape is divided into three modules named:

- MRI module,
- CT module, and
- MRI-LC module.

Each module is designed to address useful subsets of images.

V. Intended Use

PERFSCAPE V2.0 is a PACS system that allows the display, analysis and post-processing of dynamically acquired Magnetic Resonance (MRI) and Computed Tomography (CT) datasets to evaluate image intensity variations over time.

PERFSCAPE V2.0 retrieves and accepts data from existing MRI and CT systems. Based on these data, PERFSCAPE V2.0 performs quality control checks, displays Diffusion Weighted Images (MRI only) and generates parametric maps such as Relative Blood Volume, Relative Blood Flow, Relative Mean Transit Time, Time to Peak, Impulse Response Time to Peak, permeability and leakage between intravascular and extracellular space (MRI only), and temporal Maximum Intensity Projection (CT only). PERFSCAPE V2.0 also generates Diffusion Weighted Images and/or Diffusion Tensor Images (MRI only).

These images, when interpreted by a trained physician, may yield clinically useful information.

PERFSCAPE V2.0 is compliant with the DICOM standard allowing the system to visualize medical images. The system is a multiplatform software running on Windows, Mac and Linux operating systems.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

VI. Summary of the Technical Characteristics

PERFSCAPE V2.0 is a PACS software designed to access series of CT or MRI images in DICOM format. PERFSCAPE V2.0 analyzes dynamically acquired CT or MR datasets and generates parametric maps.

Used in combination with MRI datasets, PERFSCAPE V2.0 allows automatic or interactive and multiple selections of arterial input functions and displays map results of the selected slice in real time. The selected AIF can be manually filtered. It also allows generating, manually or automatically, an organ mask to remove non-organ voxels. PERFSCAPE V2.0 also allows computing DWI and DTI maps from Bxxx coregistered images.

Used in combination with CT datasets, PERFSCAPE V2.0 allows automatic or interactive and multiple selections of arterial input functions, venous output functions and displays map results of the selected slice in real time. The selected AIF can be manually filtered. It also allows generating, manually or automatically, an organ mask to remove non-organ voxels.

PERFSCAPE V2.0 allows creating a NEUROSCAPE (K083491) study with computed and/or imported maps. It also allows exporting the results as a DICOM study to the PACS or the file system.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Olea Medical
% Ms. Kristi Gusman
Project Manager
Emergo Group, Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

NOV - 4 2011

Re: K111161
Trade/Device Name: PERFSCAPE V2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 6, 2011
Received: October 7, 2011

Dear Ms. Gusman:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K111161

4. Indication for Use Statement

510(k) Number (if known): K111161

Device Name: **PERFSCAPE V2.0**

Indications for Use:

PERFSCAPE V2.0 is a PACS system that allows the display, analysis and post-processing of dynamically acquired Magnetic Resonance (MRI) and Computed Tomography (CT) datasets to evaluate image intensity variations over time.

PERFSCAPE V2.0 retrieves and accepts data from existing MRI and CT systems. Based on these data, PERFSCAPE V2.0 performs quality control checks, displays Diffusion Weighted Images (MRI only) and generates parametric maps such as Relative Blood Volume, Relative Blood Flow, Relative Mean Transit Time, Time to Peak, Impulse Response Time to Peak, permeability and leakage between intravascular and extracellular space (MRI only), and temporal Maximum Intensity Projection (CT only). PERFSCAPE V2.0 also generates Diffusion Weighted Images and/or Diffusion Tensor Images (MRI only).

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Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

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)~~ In Vitro Diagnostic Devices

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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