JUL 20 2009

K091444

510(k) Summary
(in accordance with 21 CFR 807.92)

510(k) Number K_____

I. Applicant Information

Applicant:

OLEA MEDICAL
93 avenue du Sorbier
13600 La Ciotat
France

Contact Person: Fayçal Djeridane
President
Tel: (011) 33 4 42 71 24 20
Fax: (011) 33 4 88 56 53 39
e-mail: faycal.djeridane@olea-medical.com

Application Correspondent:

EMERGO GROUP INC.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746
U.S.A.

Contact Person: Neal Kolber
Project Manager
Tel: (512) 327-9997
Fax: (512) 327-9998
e-mail: neal@emergogroup.com

Date Prepared: May 4, 2009

II. Device Name and Classification

Proprietary Name:	PERFSCAPE
Classification Name:	Magnetic Resonance Diagnostic Device
Common/Usual Name:	Picture Archiving Communications System (PACS)
Regulation Number:	892.1000
Product Codes:	LNH
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Device

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

510(k) Number:	K080762
Trade Name:	IB Neuro™ 1.0
Manufacturer:	Imaging Biometrics, LLC
Classification Name:	Magnetic Resonance Diagnostic Device
Common/Usual Name:	Picture Archiving Communications System (PACS)
Regulation Number:	892.1000
Product Codes:	LNH
Classification:	Class II

IV. Device Description

PERFSCAPE is a software application designed to analyze dynamically acquired datasets. Using well-established algorithms, parametric perfusion maps can be generated such as Relative Cerebral Blood Volume (rCBV), Relative Cerebral Blood Flow (CBF), Relative Mean Transit Time (MTT), Time to Peak (TTP) and impulse response time to peak (TMAX). The system includes critical features such as:

- Enables rapid creation of a complete array of critical perfusion parameter maps of rCBV, rCBF, rMTT, TTP, TMAX;
- Automated brain mask generation;
- View dynamic signal time course on a per-voxel basis;
- Interactive Arterial Input Function (AIF) selection;
- Export computed perfusion map to the NEUROSCAPE PACS system.

PERFSCAPE also allows the user to view the computed perfusion maps using the NEUROSCAPE software. NEUROSCAPE displays the original study series for FLAIR, ADC, B0 and B1000 and PERFSCAPE computed series for TTP, CBV, CBF, MTT and TMAX.

V. Intended Use

PERFSCAPE allows the post-processing and display of dynamically acquired Magnetic Resonance datasets to evaluate image intensity variations over time. PERFSCAPE retrieves and accepts data from existing MRI systems. Based on these data, PERFSCAPE performs quality control checks, displays Diffusion

Weighted Images and generates parametric perfusion maps such as Relative Cerebral Blood Volume (rCBV), Relative Cerebral Blood Flow (rCBF), Relative Mean Transit Time (rMTT), Time to Peak (TTP) and Impulse Response Time to Peak (TMAX). These images when interpreted by a trained physician may yield information useful in clinical applications.

PERFSCAPE is compliant with the DICOM standard allowing the system to visualize medical images. The system is a multi-platform software running on any Windows, Mac and Linux operating systems.

VI. Summary of the Technical Characteristics

PERFSCAPE is a PACS software designed to access series of MRI perfusion and diffusion images in DICOM format. PERFSCAPE analyzes dynamically acquired MR datasets and generates parametric maps of the brain.

PERFSCAPE allows 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 before the beginning of the signal of interest and after the beginning of the recirculation. It also allows generating, manually or automatically, a brain mask to remove non-brain voxels. PERFSCAPE allows creating a NEUROSCAPE study with computed perfusion maps and with imported diffusion map.

VII. Testing

OLEA Medical has conducted extensive validation testing of the PERFSCAPE system, as a software that is capable of providing reliable post-processing and display of magnetic resonance perfusion images for instantaneous multi-parametric analysis. All of the different components of the PERFSCAPE software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

VIII. Safety & Effectiveness Conclusions

Based on the comparison of intended use and technological characteristics, the PERFSCAPE system is substantially equivalent to the IB Neuro™ 1.0 device manufactured by Imaging Biometrics, LLC (K080762). The PERFSCAPE device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Olea Medical
% Mr. Neal Kolber
Project Manager
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
AUSTIN TX 78746

Re: K091444
Trade/Device Name: PERFSCAPE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 4, 2009
Received: May 21, 2009

Dear Mr. Kolber:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/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

4. Indication for Use Statement

510(k) Number (if known): K091444

Device Name: **PERFSCAPE**

Indications for Use:

PERFSCAPE allows the post-processing and display of dynamically acquired Magnetic Resonance datasets to evaluate image intensity variations over time. PERFSCAPE retrieves and accepts data from existing MRI systems. Based on these data, PERFSCAPE performs quality control checks, displays Diffusion Weighted Images and generates parametric perfusion maps such as Relative Cerebral Blood Volume (rCBV), Relative Cerebral Blood Flow (rCBF), Relative Mean Transit Time (rMTT), Time to Peak (TTP) and Impulse Response Time to Peak (TMAX). These images when interpreted by a trained physician may yield information useful in clinical applications.

PERFSCAPE is compliant with the DICOM standard allowing the system to visualize medical images. The system is a multi-platform software running on any Windows, Mac and Linux operating systems.

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 K091444