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510(K) SUMMARY

This summary is being submitted in accordance with 21 CFR 807.92.

1. GENERERAL INFORMATION

1.1. Submitter Information

Manufacturer's Name:	Invivo Corporation
Address:	N27 W23676 Paul Road Pewaukee, WI 53072
Establishment Registration #	2183683.

JUN 17 2008

1.2. Contact Person Name and Information

Contact:	Theodore J. Reisker
Title:	Director, Product Development
Company:	Invivo Corporation
Address:	N27 W23676 Paul Road Pewaukee, WI 53072
Telephone #	(262) 524-1402 ext. 175
Facsimile #:	(262) 524-1403
E-mail:	treisker@invivocorp.com

1.3. Trade name and common name of device

Trade name:	DC Neuro
Common name:	Image Processing System

1.4. Classification of the device

Classification:	Image Processing System, 21 CFR 892.2050
Class :	Class II
Procode:	LLZ

1.5. Predicate Devices

Table 1 summarizes the correspondence between various features in DC Neuro and predicate devices, along with the pertinent 510(k) submission references.

Table 1: Summary of Predicate Devices and 510(k) references

Feature	Predicate Device Name	Predicate 510(k) Submission Reference
Diffusion / FiberTrak	Philips Achieva, Intera, & Panorama 1.0T	K052078
BOLD / fMRI	Philips EasyVision Family Workstation Option - BOLD Analysis Package	K990329
Dynamic Analysis, Vessels Analysis	Philips Quantitative Analysis Package	K971965
3D Rendering	Philips EasyVision Family Workstation Option - 3D Volume Rendering	K953095
Image processing workstation	Philips View Forum	K032096

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2. BASIS FOR SUBSTANTIAL EQUIVALENCE DETERMINATION

2.1. Device Description

2.1.1. Summary of device functions and the devices major components

DC Neuro is a software package available for viewing, printing, storing, transferring, and quantifying DICOM magnetic resonance imaging (MRI) studies. The DC Neuro software is able to run on "off the shelf" standard PC components using the Microsoft Windows XP Professional Operating Software.

DC Neuro provides both analysis and viewing capabilities that integrate both anatomical and physiologic/functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI, diffusion, fiber tracking, dynamic analysis, and vessel analysis in both 2D and/or 3D views.

DC Neuro software provides automated processing of DICOM images. Imaging exams are transferred to the DC Neuro system in DICOM format either directly from the MR system or from a picture archiving and communications system (PACS) or via supported digital media. The DC Neuro system reads the incoming image headers and automatically sorts the images into exams consisting of multiple data sets. Pre-set processing algorithms may be performed on the incoming data as defined by the user such as image co-registration, fMRI analysis, diffusion analysis, dynamic analysis, vessel analysis, and 3D displays.

2.1.2. Description of device (major components)

DC Neuro is a software package that uses standard PC hardware, with a standard user/operator interface (keyboard and mouse), and a standard Operating System: Microsoft Windows XP Professional.

2.2. Intended use

DC Neuro is an image processing software package designed to run on standard PC hardware (workstation). The required workstation hardware consists of standard, "off-the-shelf" computer components. DC Neuro software receives image data from medical imaging devices such as Magnetic Resonance Imaging systems or from image archives, PACS. DC Neuro can be used to perform image viewing, image manipulation, image quantification, communication, and printing.

DC Neuro provides both analysis and viewing capabilities which integrate both anatomical and physiologic/functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI, diffusion, fiber tracking, dynamic analysis, and vessel analysis in both 2D and/or 3D views.

BOLD fMRI: The BOLD analysis is useful in quantifying small susceptibility changes in the human brain, created by the execution of a specific task.

Diffusion/Fiber tracking: The diffusion of water molecules through brain tissue can be measured with diffusion-weighted MRI scanning. Actual diffusion properties depend on the local tissue. With fiber tracking, the directional dependency can be used to visualize the white matter structure in the brain.

Dynamic Analysis: Dynamic analysis is intended for visualization and analysis of MR dynamic studies, showing changes in contrast over time, where such techniques are useful or necessary.

Vessel Analysis: Allows the visualization of vascular morphology from contrast-enhanced MR images.

3D Visualization: 3D rendering allows the visualization of bone, vascular structures, and selected anatomy as three dimensional object surfaces projected on a flat screen.

2.3. Safety Information

No new hazards are introduced by Invivo Corporation's DC Neuro, as compared to predicated devices and image processing functionality.

2.4. Conclusion

Invivo Corporation's DC Neuro is substantially equivalent to the Philips ViewForum 2003 workstation, and the Philips BOLD fMRI, Diffusion/Fiber Tracking, Dynamic and Vessel Analyses, and 3D visualization image processing functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Invivo Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K081262
Trade/Device Name: DC Neuro
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 5, 2008
Received: June 6, 2008

Dear Mr. Job:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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

INDICATIONS FOR USE

510(k) Number (if known): K081262

Device Name: DC Neuro

Indications For Use:
DC Neuro is an image processing software package designed to run on standard PC hardware (workstation). The required workstation hardware consists of standard, "off-the-shelf" computer components. DC Neuro software receives image data from medical imaging devices such as Magnetic Resonance Imaging systems or from image archives, PACS. DC Neuro can be used to perform image viewing, image manipulation, image quantification, communication, and printing.

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3D Visualization: 3D rendering allows the visualization of bone, vascular structures, and selected anatomy as three dimensional object surfaces projected on a flat screen.

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 K081262