MAR - 9 2009

prism®

5 510(k) Summary

K082964 – Prism Acquire®, Prism Process®, Prism View®

1. Contact Information

Submitter
Prism Clinical Imaging, Inc.
10437 Innovation Dr., Suite 403
Wauwatosa, WI 53226

Contact Person
James L. Reuss, Ph.D. (CTO)
Phone 414-727-1930
Fax 414-727-1939

Date Summary Prepared: September 29, 2008; rev. February 13, 2009

2. Device Name and Classification

Trade Name	*Classification Name*	*Class*	*Product Code*
Prism Acquire	892.1000, "Radiology, Magnetic Resonance Diagnostic Device"	II	LNH
Prism Process	892.1000, "Radiology, Magnetic Resonance Diagnostic Device"	II	LNH
Prism View	892.2050, "Picture archiving and communications systems"	II	LLZ

3. Identification of Legally Marketed Equivalent Predicate Devices

Predicate System	*Manufacturer*	*Reg. Data*
BrainAcquireRx™, BrainProcessRx™	Prism Clinical Imaging, Inc. 10437 Innovation Dr., Suite 403 Wauwatosa, WI 53226 (f/k/a Kyron Clinical Imaging)	K061255 SE 6/13/2006 Product code LNH Class II
BrainViewRx™ (a/k/a Prism View)	Prism Clinical Imaging, Inc. 10437 Innovation Dr., Suite 403 Wauwatosa, WI 53226 (f/k/a Kyron Clinical Imaging)	K052467, K063031 SE 12/20/05,11/2/06 Product code LLZ Class II
Syngo® Multimodality Workstation	Siemens Medical Systems 186 Wood Ave. South Iselin, NJ 08830	K010938 SE 6/26/2001 Product code LLZ Class II
Advantage Windows with FuncTool Option	GE Medical Systems 3000 N. Grandview Blvd Waukesha, WI 53188	K960265 SE 7/3/1996 Product code LLZ Class II

prism®

4. Description of Device

Prism Acquire provides a scripted approach to performing fMRI and other imaging studies. Prism Process performs post-processing and quality assurance of fMRI and other imaging data sets. The processed data is prepared for report generation utilizing the Prism View product, supporting the visualization and manipulation of clinical imagery of multiple kinds. It provides a flexible set of display, analysis, and export options for utilizing the imagery relationships.

These applications may communicate in the healthcare IT environment via Prism Flow®, server-based software facilitating DICOM communications, authorization/authentication, audit logging, and other infrastructure functions.

5. Statement of Intended Use

Prism Acquire® / Prism Process® software is used in conjunction with a Magnetic Resonance scanner to acquire and process blood oxygen level dependent (BOLD) functional magnetic resonance imaging (fMRI) and other MRI data sets. Prism View® software provides visualization of anatomical with functional and physiologic imaging data sets.

Prism Acquire presents a scripted series of synchronized visual and/or auditory stimuli and/or cognitive/motor tasks to the patient being scanned. The patient's responses and image data from the MRI scanner are stored for use by Prism Process, which performs post-processing for quality control and subsequent viewing of fMRI and other data. These applications can also be used to assist in scripted data acquisition and post-processing of other anatomical, functional and physiologic MR imagery including magnetic resonance spectroscopy (MRS), MR perfusion, and MR diffusion.

Prism View provides both analysis and viewing capabilities that promote the integration of anatomical with physiologic and functional imaging data sets including blood oxygen level dependent (BOLD) fMRI, magnetic resonance spectroscopy (MRS), MR perfusion, and MR diffusion including diffusion tensor imaging (DTI).

The integration of these data, when interpreted by a trained physician, yields information that may assist in the diagnosis of central nervous system pathology and the planning and monitoring of medical treatments.

prism®

6. Predicate Device Comparison of Technological Characteristics

The technological characteristics of Prism Acquire, Process and View are the same as the respective original devices. Incremental revisions to the software have been made, including adoption of DICOM standard communications.

The MR perfusion capability added to the indications for use is substantially equivalent to the corresponding features found in the Neuro Perfusion option of the syngo® predicate device, and the GE Advantage workstation with FuncTool option.

7. Performance Study

FDA has not established special controls or performance standards for this device. Software verification and validation was conducted to confirm proper function of the device's features.

8. Safety information

No new safety hazards are introduced by the use of the device in comparison to the software of the predicate devices.


prism®

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2009

James L. Reuss, Ph.D.
Chief Technology Officer
Prism Clinical Imaging, Inc.
10437 Innovation Dr., Suite 403
WAUWATOSA WI 53226

Re: K082964
Trade/Device Name: Prism Acquire®, Prism Process®, and Prism View®
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 13, 2009
Received: February 20, 2009

Dear Dr. Reuss:

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

4 Indications For Use

510(k) Number (if known): K082964

Device Name: Prism Acquire®, Prism Process®, Prism View®

INDICATIONS FOR USE:

Prism Acquire® / Prism Process® software is used in conjunction with a Magnetic Resonance scanner to acquire and process blood oxygen level dependent (BOLD) functional magnetic resonance imaging (fMRI) and other MRI data sets. Prism View® software provides visualization of anatomical with functional and physiologic imaging data sets.

Prism Acquire presents a scripted series of synchronized visual and/or auditory stimuli and/or cognitive/motor tasks to the patient being scanned. The patient's responses and image data from the MRI scanner are stored for use by Prism Process, which performs post-processing for quality control and subsequent viewing of fMRI and other data. These applications can also be used to assist in scripted data acquisition and post-processing of other anatomical, functional and physiologic MR imagery including magnetic resonance spectroscopy (MRS), MR perfusion, and MR diffusion.

Prism View provides both analysis and viewing capabilities that promote the integration of anatomical with physiologic and functional imaging data sets including blood oxygen level dependent (BOLD) fMRI, magnetic resonance spectroscopy (MRS), MR perfusion, and MR diffusion including diffusion tensor imaging (DTI).

The integration of these data, when interpreted by a trained physician, yields information that may assist in the diagnosis of central nervous system pathology and the planning and monitoring of medical treatments.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use _____ (Per 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 K082964