K122026

SEP 21 2012

6 Special 510(k) Summary

K_____ – Prism Acquire®, Prism Process®, Prism View®

1. Contact Information

Submitter
Prism Clinical Imaging, Inc.
890 Elm Grove Rd. Ste. 215
Elm Grove, WI 53122

Contact Person
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Phone 262-754-3840
Fax 262-754-3839

Date Summary Prepared: June 21, 2012

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 Modified Predicate Device

Predicate System	*Manufacturer*	*Reg. Data*
Prism Acquire®, Prism Process®, Prism View®	Prism Clinical Imaging, Inc. 890 Elm Grove Rd. Ste. 215 Elm Grove, WI 53122 (f/k/a Kyron Clinical Imaging)	K082964 SE 2/20/2009 Product code LNH, LLZ Class II

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.

6. Predicate Device Comparison of Technological Characteristics

The intended uses and technological characteristics of Prism Acquire, Process and View are the same as the respective predicate devices. Incremental revisions to the software have been made, including the following:

1) Expanded selection of fMRI paradigms, including additional natural languages;

2) Improved tools for report workflow, including report creation and addition of image data to existing reports;

3) Expanded registration of MR, CT, and PET image combinations, including handling of scanner obliquity;

4) Enhancement of DTI visualization to include additional parameter maps and diffusion tensor tractography (DTT);

5) Addition of volume rendering and track markups to 3D visualization options;

6) Support for MR Arterial-Spin Labeled (ASL) perfusion images in the MR perfusion visualization;

7) Expanded selection of image markup tools.

None of these features represent fundamentally new scientific technology.

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.

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

SEP 21 2012

James L. Reuss, PhD
Chief Technology Officer
Prism Clinical Imaging, Inc.
890 Elm Grove Road, Suite 215
ELM GROVE WI 53122

Re: K122026
Trade/Device Name: Prism Acquire®, Prism Process®, Prism View®
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and LLZ
Dated: August 23, 2012
Received: August 29, 2012

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 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.

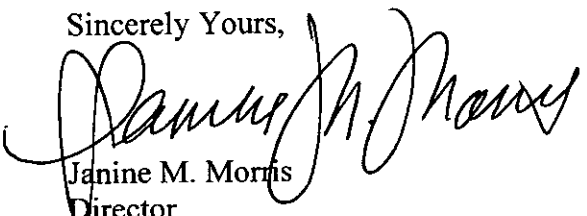
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5 Indications For Use

510(k) Number (if known): K_____

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

INDICATIONS FOR USE:

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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 Radiological Devices
OIVD
510k K120088