K063031

NOV - 2 2006

5 510(k) Summary

Special 510(k) K_____ – Kyron™ Clinical Imaging Prism View™

1. Contact Information

Submitter
Kyron Clinical Imaging, Inc.
2457 N. Mayfair Rd., Suite 202
Wauwatosa, WI 53226

Contact Person
James L. Reuss, Ph.D.
Phone 414-727-1930
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Date Summary Prepared: September 1st 2006

2. Device Name and Classification

The proprietary name of the device to be introduced into interstate commerce is the Prism View software package. It is image processing software running on a personal computer platform, and is classified under regulatory product code 90 LLZ (regulation # 892.2050), "Picture archiving and communications systems" as a class II medical device.

3. Identification of Legally Marketed Equivalent Predicate Devices

Predicate System	*Manufacturer*	*Reg. Data*
BrainViewRx™ (a/k/a Prism View)	Kyron Clinical Imaging, Inc. 2457 N. Mayfair Rd., Suite 202 Wauwatosa, WI 53226	K052467 SE 12/20/2005 Product code LLZ Class II

4. Description of Device

Prism View is an image processing software package for the visualization and manipulation of clinical imagery of multiple kinds. It brings sets of anatomical, physiologic and/or functional imagery into alignment and provides a variety of display and analysis options for utilizing the imagery relationships.

5. Statement of Intended Use

"Prism View™ provides visualization of functional and physiologic brain imaging data. The software package provides both analysis and viewing capabilities that promote the integration of physiologic and functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI, magnetic resonance spectroscopy (MRS), 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 brain pathology and the planning and monitoring of medical treatments."

6. Predicate Device Comparison of Technological Characteristics

The technological characteristics of Prism View are the same as the original device. Incremental revisions to the software have been made.

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 Prism View software package in comparison to the software of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Michael Schmainda
President & Chief Operating Officer
Kyron Clinical Imaging, Inc.
2457 N. Mayfair Road, Suite 202
WAUWATOSA WI 53226

NOV - 2 2006

Re: K063031
Trade/Device Name: Kyron™ Clinical Imaging, Inc. – Prism View™
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2006
Received: October 3, 2006

Dear Mr. Schmainda:

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 (Premarket Approval), 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 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 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

4 Indications For Use

510(k) Number (if known): K 063031

Device Name: Kyron™ Clinical Imaging, Inc. – Prism View™

INDICATIONS FOR USE:

Prism View™ provides visualization of functional and physiologic brain imaging data. The software package provides both analysis and viewing capabilities that promote the integration of physiologic and functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI, magnetic resonance spectroscopy (MRS), 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 brain 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063031