

5 510(k) Summary

K_____ – BrainAcquireRx™ / BrainProcessRx™ Data Suite JUN 13 2006

1. Contact Information

Submitter

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

Contact Person

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

Date Summary Prepared: May 1st, 2006

2. Device Name and Classification

The proprietary name of the device to be introduced into interstate commerce is the BrainAcquireRx™ / BrainProcessRx™ Data Suite. It is image reconstruction and processing software running on a personal computer, classified under product code 90 LNH (regulation # 892.1000), "Radiology, Magnetic Resonance Diagnostic Device" as a class II medical device.

3. Identification of Legally Marketed Equivalent Predicate Devices

<i>Predicate System</i>	<i>Manufacturer</i>	<i>Reg. Data</i>
Eloquence Integrated Functional Imaging System	MRI Devices Corp. 1515 Paramount Dr. Waukesha, WI 53186	K023130 SE 10/11/2002 Product code LNH Class II
MindState™ Functional Data Acquisition Device (fDAD™)	Neurognostics, Inc. 10437 Innovation Dr., Suite 309 Milwaukee, WI 53226	K043290 SE 1/28/2005 Product code LNH 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
Diffusion tensor imaging option for MRI	GE Medical Systems P.O. Box 414, W-709 Milwaukee, WI 53201	K003573 SE 1/23/2001 Product code LNH Class II

4. Description of Device

The software provides support for functional MRI (fMRI) data acquisition and post-processing, as well as other anatomical, functional and physiologic MRI



studies. BrainAcquireRx provides a scripted approach to performing fMRI and other functional, anatomical and physiologic MRI studies. BrainProcessRx performs post-processing of fMRI and other data sets. The processed data is ready for report generation utilizing the Kyron BrainViewRx™ Viewer.

5. Statement of Intended Use

“The BrainAcquireRx™ / BrainProcessRx™ Data Suite is software 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.

The BrainAcquireRx software application 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 the BrainProcessRx application, which performs post-processing for quality control and subsequent viewing of fMRI and other MRI data. These applications can also be used to assist in scripted data acquisition and post-processing of anatomical, functional, and physiologic MR imagery including magnetic resonance spectroscopy (MRS) and MR diffusion. 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 BrainAcquireRx application contains fMRI stimulus, acquisition and post-processing capabilities that are substantially equivalent to the software provided with the MRI Devices Eloquence and the Neurognostics MindState workstations. BrainProcessRx also performs post-processing of other MRI data sets substantially equivalent to the MRI data post-processed by the Siemens *syngo* software and GE DTI 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 13 2006

James L. Reuss, Ph.D.
Chief Technology Officer
Kyron Clinical Imaging, Inc.
2457 N. Mayfair Rd., Suite 202
WAUWATOSA WI 53226

Re: K061255

Trade/Device Name: BrainAcquireRx™ / BrainProcessRx™ Data Suite
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: May 1, 2006
Received: May 4, 2006

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 (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.



Protecting and Promoting Public Health

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
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 061255

Device Name: BrainAcquireRx™ / BrainProcessRx™ Data Suite

INDICATIONS FOR USE:

The BrainAcquireRx™ / BrainProcessRx™ Data Suite is software 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.

The BrainAcquireRx software application 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 the BrainProcessRx application, 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) and MR diffusion. 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.

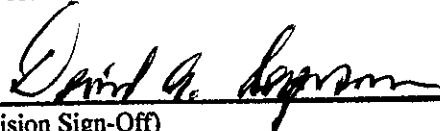
Prescription Use X
(Per 21 CFR 801 Subpart D)

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)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K061255