DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Brainreader ApS
C/O Mette Munch
QA Consultant
Skagenvej 21
Egaa, 8250
DENMARK

February 4, 2015

Re: K140828
Trade/Device Name: NeuroReader Medical Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, LNH
Dated: January 15, 2015
Received: January 28, 2015

Dear Mette Munch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140828

Device Name
NeuroReader Medical Image Processing Software

Indications for Use *(Describe)*

The NeuroReader Medical Image Processing Software is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) summary – Neuroreader Medical Image Processing Software

Administrative information:

Name:	Brainreader Aps
Address:	Emil Møllers Gade 41a
	DK-8700 Horsens
	Denmark
Contact person:	Mette Munch, QA Consultant
Cell phone:	+45 29872000
E-mail:	mm@addaction.dk

Date of summary: 15-Jan-2015

Name of device:
Trade name: Neuroreader medical Image Processing Software
Common name: Neuroreader
Classification name: Picture archiving and communication system (LLZ)

Predicate device:

510(k) reg. no	Manufacturer	Device	Product code
K061855	CorTechs Labs, Inc.	NeuroQuant™ Medical Image Processing Software	LLZ

Device description:

Neuroreader is a medical image processing software intended for automatic labeling, visualization and volumetric quantification of identifiable brain structures from magnetic resonance images. The segmentation system relies on a number of atlases which each consist of a T1-weighted MR image, a binary mask covering the brain and a label map dividing the MR image into different anatomical segments.
Neuroreader provides an estimation of the normal volume for a person with similar demographic data. This is done based on a statistical model and a database of healthy material. Neuroreader is intended to automate the current manual process of identifying, labeling and quantifying the volume of brain structures identified on MR images. Neuroreader is aimed to be a support tool for clinicians

in assessing structural MRIs. Neuroreader describes the analysis results in a self-explicative volumetric report within an analysis-time of 10 minutes.

Intended use:

The Neuroreader Medical Image Processing Software is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.

Comparison to Predicate Device:

Table 1: Comparison between Neuroreader Medical Image Processing Software and K061855: NeuroQuant™ medical Image Processing Software.

	Neuroreader Medical Image Processing Software	**NeuroQuant™ medical Image Processing Software – K061855**
Indications for use	The Neuroreader Medical Image Processing Software is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.	NeuroQuant™ is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.

Summary of technical characteristics of device compared to predicate device:

The device and predicate device (K061855) have identical:

- Regulation name: “Picture archiving and communication system”,
- Regulation number: 21 CFR 892.2050
- Regulatory Class: II
- Product code: LLZ

Device and predicate device are software for measuring brain MRI volume, automatic labeling and visualization. The output volumes are then compared to a normative dataset computed based on MRI data from normal control subjects.

Neuroreader™ and Neuroquant achieve their intended use based on a similar principle, as the segmentation system relies on a number of atlases which each consist of a T1-weighted MR image, a binary mask covering the brain and a label map dividing the MR image into different anatomical segments. Analysis requires a T1 weighted MRI that includes nose, ears, and vertex without wraparound. All atlases must agree on which label values belong to which segments. For this purpose the standards implemented in the Freesurfer project are used. Image transformation use discrete cosine nonlinear registration to a probabilistic atlas.

Device and predicate device upload MR image to the analysis server, do automatic brain segmentation and determine the volume of brain structures. The MR image goes through filtering, a gradient non-linearities- and field inhomogeneities artifact correction as well as a skull stripping step.

Device and predicate device use the intra-cranial volume as a reference in the statistical calculations. The output compares an individual patient's regional brain volumes with those of a normative database, correcting for sex, head size, and age. Both devices generate a report with similar output parameters.

Summary of substantial equivalence based on clinical data: In order to validate the segmentation quality of Neuroreader™ fully automated brain segmentation, 100 images of the manually segmented AEAD-ADNI Hippocampal segmentation protocol dataset was used as the ground truth. Neuroreader™ can segment the hippocampus with a Dice similarity index of 0.87 for both the right and left hippocampus. The Dice similarity reaches a maximum of 0.91. The validation indicates that Neuroreader is safe to use.

<u>Conclusion on substantial equivalence based on technical comparison and clinical data:</u>

By virtue of the physical characteristics and intended use, Neuroreader™ is substantially equivalent to a device legally cleared to be marketed in the United States.

The conclusion drawn from the non-clinical and clinical performance data, shows that the device is as safe, as effective, and performs as well as the predicate device and the state of the art manual segmentation process.