



Food and Drug Administration
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Silver Spring, MD 20993-0002

icometrix NV
% Mr. Dirk Loeckx
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BELGIUM

August 9, 2016

Re: K161148
Trade/Device Name: icobrain
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 30, 2016
Received: June 30, 2016

Dear Mr. Loeckx:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a large, semi-transparent watermark of the FDA logo.

For

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

Enclosure

Indications for Use

510(k) Number (if known)
K161148

Device Name
icobrain

Indications for Use (Describe)

icobrain 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.

icobrain consists of two distinct image processing pipelines: icobrain cross and icobrain long.

- Icobrain cross is intended to provide volumes from images acquired at a single timepoint
- icobrain long is intended to provide changes in volumes between two images that were acquired on the same scanner, with the same image acquisition protocol and with same contrast at two different timepoints

The results of icobrain cross cannot be compared with the results of icobrain long.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5. 510(k) Summary

- 5.1 Submitter
- 5.2 Device
- 5.3 Predicate Device
- 5.4 Device Description
- 5.5 Intended use
- 5.6 Comparison of technological characteristics with the predicate device
- 5.7 Performance testing

5.1 Submitter

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Date Prepared:	 21 Jun 2016

5.2 Device

Device Trade Name:	icob rain
Common Name	Medical Image Processing Software
Classification Name	System, Image processing, Radiological
Number	892.2050
Product Code:	LLZ
Classification Panel:	Radiology

5.3 Predicate Device

Device	NeuroQuant™
510(k) Number	K061855
Manufacturer	CorTechs Labs, Inc. 4690 Executive Drive, Suite 250 San Diego, CA 92121 USA

5.4 Device Description

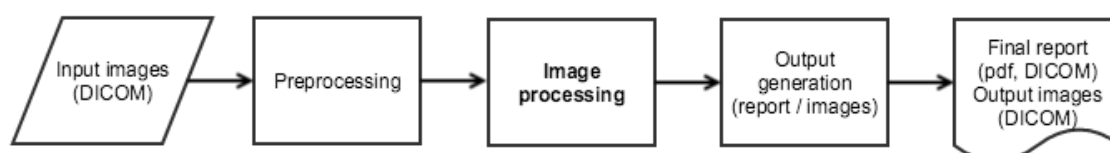
icobrain is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified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

icobrain consists of two distinct image processing pipelines: **icobrain cross** and **icobrain long**.

- **icobrain cross** is intended to provide volumes from images acquired at a single timepoint
- **icobrain long** is intended to provide changes in volumes between two images that were acquired on the same scanner, with the same image acquisition protocol and with same contrast at two different timepoints

The results of **icobrain cross** cannot be compared with the results of **icobrain long**.

The following flowchart illustrates the overall architecture of **icobrain**.



As input, **icobrain** uses T1-weighted and fluid-attenuated inversion recovery (FLAIR) DICOM MR images from a single or from multiple time points. In case of multiple time points, i.e. multiple MRI scans from the same subject, for each time point one FLAIR and one T1 image are used as input. During the pre-processing, the scan type (T1, FLAIR) is detected for every input image before it is converted from DICOM format to NIFTI format. The image processing then performs the actual segmentation and calculates the volumes of the brain structures. In case MRI scans from the same subject on multiple time points are available, the changes in volume of the brain structures are calculated as well. Finally, the computed volumes and volume changes (in case of multiple time points) are summarized into an electronic report and (some) segmentations are overlaid on the input images.

The software displays the following volumetric measures:

- normalized volume and volume changes of the whole brain (sum of white and grey matter),
- normalized volume and volume changes of grey matter,
- unnormalized volume and volume changes of FLAIR white matter hyperintensities.

Normalized whole brain and grey matter volumes are corrected for head size and are compared to a healthy population using a statistical model. The reported FLAIR white matter hyperintensities volumes are not normalized since they are not comparable to a reference population.

5.5 Intended use

icobrain 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.

5.6 Comparison of technological characteristics with the predicate device

The device and predicate device (K061855) have an identical classification of:

Device	icobrain	NeuroQuant™
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological
Product Code	LLZ	LLZ
Regulatory Class	II	II
Indications for use	<p>icobrain 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.</p> <p>icobrain consists of two distinct image processing pipelines: icobrain cross and icobrain long.</p> <ul style="list-style-type: none"> • icobrain cross is intended to provide volumes from images acquired at a single timepoint • icobrain long is intended to provide changes in volumes between two images that were acquired on the same scanner, with the same image acquisition protocol and with same contrast at two different timepoints <p>The results of icobrain cross cannot be compared with the results of icobrain long.</p>	<p>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 segmental brain structures identified on MR images.</p>

Table I: Comparison with predicate device

Device and predicate device are software for automatically identifying and quantifying the volumes of brain structures, automatic labeling and visualization. Both devices take 3D MR images of the brain as input and generate an electronic report with similar quantitative information. The output volumes are for both devices compared to a normative dataset computed based on MRI data from normal control subjects.

icobrain and NeuroQuant™ achieve their intended use based on a similar principle, since the quantification system relies on skull stripping (brain extraction), a brain segmentation based on a

probabilistic atlas and image intensity information, and volume calculations of the segmented brain structures. Both devices normalize the volumes to allow the statistical comparison with a normative dataset.

Both devices are DICOM compatible and operate on off-the-shelf hardware.

icobrain is used by trained professionals in hospitals, imaging centers or in image processing labs.

NeuroQuant™ is used by physicians skilled in brain MR imaging.

5.7 Performance testing

To demonstrate the performance of icobrain, the measured volumes and volume changes of the segmentable brain structures are validated for accuracy and reproducibility. The subjects upon whom the device was tested include healthy subjects, Alzheimer's disease patients, multiple sclerosis patients, traumatic brain injury patients, depression patients.

In the accuracy experiments, the volumes / volume changes are compared to simulated and/or manually labeled ground truth volumes / volume changes; in the reproducibility experiments, the volumes / volume changes are compared on test-retest image data sets. A literature review has been performed to set relevant acceptance criteria for each type of experiment. All experiments passed the acceptance criteria.

The experiments encompassed 349 subject datasets in total. Averaged over all experiments, the Pearson correlation coefficient between the compared measurements was 0.90 and the intraclass correlation coefficient was 0.89.

Besides the validation experiments, verification tests demonstrate the system as a whole provides all the capabilities necessary to operate according to its intended use.

5.8 Conclusions

The performance testing presented above establishes that the icobrain is safe and effective for its intended use. The comparison above demonstrates that the icobrain device is substantially equivalent to the predicate device.

Declarations:	<ul style="list-style-type: none">● This summary includes only information that is also covered in the body of the 510(k).● This summary does not contain any puffery or unsubstantiated labeling claims.● This summary does not contain any raw data, i.e., contains only summary data.● This summary does not contain any trade secret or confidential commercial information.● This summary does not contain any patient identification information.
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This document is reviewed and approved by Dirk Loeckx, CEO of icometrix, based on the present data and information.

Signature

A handwritten signature in black ink, appearing to be a stylized name or set of initials.

Date

 04 Aug 2016