510(k) summary – Neuroreader Medical Image Processing Software

Administrative information:

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

Predicate device:

<table>
<thead>
<tr>
<th>510(k) reg. no</th>
<th>Manufacturer</th>
<th>Device</th>
<th>Product code</th>
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<tbody>
<tr>
<td>K061855</td>
<td>CorTechs Labs, Inc.</td>
<td>NeuroQuant™ Medical Image Processing Software</td>
<td>LLZ</td>
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</table>

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.

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<th>Neuroreader Medical Image Processing Software</th>
<th>NeuroQuant™ medical Image Processing Software – K061855</th>
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<tr>
<td><strong>Indications for use</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
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**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.

Conclusion on substantial equivalence based on technical comparison and clinical data:

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.