DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 7, 2016

ZepMed, LLC.
% Mr. James Monroe
CEO
Monroe Medical Device Consulting, LLC
319 Shilling Drive
SOMERSET NJ 08873

Re: K161322
Trade/Device Name: CT CoPilot™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 11, 2016
Received: November 14, 2016

Dear Mr. Monroe:

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,

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

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 below.

510(k) Number *(if known)*

K161322

Device Name
CT CoPilot™

Indications for Use *(Describe)*

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CT CoPilot™ is intended for automatic labeling, visualization and volumetric quantification of segmentable structures from sets of CT images of the brain. This software is intended to automate the current manual process of identifying, labeling and quantifying structures identified on CT images of the brain and to provide automated registration and reformatting of data.

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.

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

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05 - 510k Summary

CT Co-Pilot

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:
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Contact Person: James W. Monroe;
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Date Prepared: November 11, 2016

Name of Device and Name/Address of Sponsor

CT CoPilot™
ZepMed, LLC.
2465 Avenida de La Playa
La Jolla, CA 92037

Common or Usual Name
Picture Archiving and Communication System

Classification Name
System, Image Processing, Radiological (892.2050)

Classification Panel
Radiology

Product Codes
LLZ

Device Class
II

Predicate Devices
NeuroQuant (K061855)

Intended Use / Indications for Use

CT CoPilot™ is intended for automatic labeling, visualization and volumetric quantification of segmentable structures from sets of CT images of the brain. This software is intended to automate the current manual process of identifying, labeling and quantifying structures identified on CT images of the brain and to provide automated registration and reformatting of data.

Device Description

CT CoPilot™ is intended for use in automating post-acquisition quantitative analysis of CT images of the brain for patients aged 18 or older. CT CoPilot™ performs automatic reformatting, labeling and quantification of segmentable structures from a set of CT images. Output of the software provides these values as numerical volumes and images which have been annotated with graphical color overlays, with each color representing a specific segmental structure. When CT imaging is performed more than once on a patient, the current data is co-registered to the most recent processed prior exam of the same patient, facilitating comparison between the studies using CT CoPilot™. Voxel-by-voxel subtraction maps of the pixel density change in Hounsfield Units (HU) are generated in up to 3 dimensions between the current and most recent processed prior exam of the patient.

CT CoPilot™ incorporates registration, alignment, and segmentation methods similar to a previous 510(k) cleared device, known as NeuroQuant (K061855), to automatically label and quantify the volume of segmentable structures in MRI images of the head. CT CoPilot™ output is provided in standard DICOM format as additional series of images (with appropriate descriptors) and reports that can be displayed on most third-party commercial DICOM workstations. CT CoPilot™ is intended to provide visualization and quantification data for CT scans of the brain. CT CoPilot™ includes safety procedures and error reporting similar to those adopted by NeuroQuant to identify cases that may not be processed for any reason. CT CoPilot™ is intended to be used by trained personnel in Neuro CT imaging. Patient management decisions should not be made based solely on the results of CT CoPilot™ quantitative data.

In laboratory testing, CT CoPilot™ demonstrates the following registration accuracy based on 100 randomly acquired CT head scans on both normal patients and those with abnormal

pathologies: 1) The inter-subject variability of the angle formed by the inter-hemispheric plane and the vertical line, as measured on axial views (yaw), is less than 15 degrees. 2) The inter-subject variability of the positioning of the inter-hemispheric plane and the vertical line, as measured on coronal views (roll), is less than 15 degrees. 3) The inter-subject variability of the positioning of the AC/PC plane and the horizontal line, as measured on sagittal views, is less than 15 degrees. Laboratory testing of CT CoPilot™ software on 179 scans from 34 patients with ventriculostomy catheters demonstrates the following correlation coefficients between the automatic software segmentation accuracy of relevant anatomical structures when compared against the same group of medical expert manually segmented subjects: (Lateral Ventricle Volume = 98%, Total CSF Volume = 98%, Intra-Cranial Volume = 99%, Midline Shift Index = 95%). Laboratory testing of CT CoPilot™ segmentation reliability demonstrates equivalent test-retest performance as expert manually segmented subjects. The accuracy testing of CT CoPilot™ registration and segmentation performance was similar to the predicate device (NeuroQuant) without additional safety risk.

CT CoPilot™ consists of proprietary software developed by ZepMed, Inc. installed on an off-the-shelf personal computer. The output of CT CoPilot™ is intended for Picture Archive and Communications System (PACS) display systems. PACS display systems must contain sufficient functionality to display color images (either MR or Secondary Capture), and to display report text and graphics output either in DICOM Structured Report or display of Adobe PDF or JPEG files.

The accuracy of the automatic cross-sectional registration and segmentation in CT CoPilot™ is affected by the subject's deviation from the features embedded in the reference neuroanatomic Atlas. In general, the accuracy of the CT CoPilot™ system software may decrease when the subject’s head includes pathologic features not present in the Atlas, lacks features present in the Atlas, or is structurally different than that defined in the pre-existing neuroanatomic Atlas. The accuracy of the CT CoPilot™ single image and serial image analysis program may also be degraded by patient motion or by artifacts which are introduced into the patient scanning process, or if patient positioning severely deviates from expectations. Alignment of subject to Atlas space is an important software step in the overall process of registration and segmentation. CT CoPilot™ uses the mechanism for

determination of alignment accuracy instantiated in the predicate device (NeuroQuant) for establishing the relationship between image quality and overall alignment accuracy. Specifically, a "measurement index" is determined for each study based on the deviation of each image from the normalized anatomic index embedded in the program. The measurement index is determined by the deviation of the image volumes from normal atlas space. The automatically determined "measurement index" is used to define the limit of anatomic alignment variance which has been determined through laboratory testing of CT CoPilot™ to be accepted by the program. As a safety feature, the CT CoPilot™ software calculates and reports a measurement index number which reflects the adequacy of overall single image and serial image alignment. If the measurement index exceeds specified limits, an error report is generated to inform the user and further processing is terminated.

Factors that may degrade the technical quality and accuracy of CT CoPilot™ registration and segmentation results include:

a) Patient's motion during scan.
b) Artifacts affecting overall image quality.
c) Reconstruction artifacts.
d) Pathological and or anatomical deviations from the Atlas.
e) Large initial alignment deviations between the patient and the Atlas.

Non-Clinical Testing

- ISO 14971 Second Edition 2007, Medical Devices - Application Of Risk Management To Medical Devices.
- ISO 62304: The Harmonized Standard for Medical Device Software Development
- NEMA PS 3.1 - 3.20 (2011), Digital Imaging And Communications In Medicine (Dicom) Set.

Comparison to Predicate Device

ZepMed's CT CoPilot™ , is substantially equivalent to the predicate devices listed below with respect to intended use/indications for use, principles of operation and technological characteristics.

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Substantial Equivalence Table

Attribute	**CT CoPilot™**	**NeuroQuant**	**Equivalence**
510(k)	**(Subject Device)**	**K061855**	
Product Code	LLZ	LLZ	Yes
Intended Use	CT CoPilot™ is intended for automatic labeling, visualization and volumetric quantification of segmentable structures from sets of CT images of the brain. This software is intended to automate the current manual process of identifying, labeling and quantifying structures identified on CT images of the brain and to provide automated registration and reformatting of data.	NeuroQuant™ is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from sets 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.	Yes
Data Source	CT Scanner	MRI Scanner	Different
Display images	Reformatted, realigned axial, coronal, and sagittal images.	Reformatted, realigned axial, coronal and sagittal images.	Yes
Quantitative Metrics	CSF volumes, Intracranial volume, Midline shift.	CSF volumes, Intracranial volume, Brain structure volumes.	Similar

Physical Characteristics	• Software package • Operates off-the-shelf software (multiple vendors)	• Software package • Operates off-the-shelf software (multiple vendors)	Yes
Operating System	OS:Linux	OS: Linux,Mac,Windows	Yes
DICOM compatible	Yes	Yes	Yes
Performance measurement Testing	Reproducibility and Accuracy testing	Reproducibility and Accuracy testing	Yes
Safety	Measurement data can be viewed, accepted or rejected by a physician	Measurement data can be viewed, accepted or rejected by a physician	Yes
In plane voxel Resolution (Input Data)	0.1-1mm	1mm	Similar
Slice Thickness (Input Data)	0.2-1mm	1.2mm	Similar
Automatic Alignment	Yes	Yes	Yes
Registration Target Data	Atlas, Prior	Atlas	Similar
Skull Stripping	Yes	Yes	Yes
Automatic Segmentation	Yes	Yes	Yes
Error Detection	Yes	Yes	Yes
Output Image Data Format	3D Volumetric, 2D MPR -1mm isotropic volume -1-5mm thick MPR	3D Volumetric -1mm isotropic volume	Similar
Color-coded Segmentation Series (Output Data)	Yes	Yes	Yes

Substantial Equivalence Discussion:

Both CT CoPilot™ and NeuroQuant (K061855) allow for the visualization and volumetric quantification of brain images. Similarly, both systems incorporate post-acquisition quantitative analysis of acquired images and transform and display the results in DICOM standard formatted images and reports. Both systems perform reproducibility and accuracy testing. The difference between the post processing systems is that CT CoPilot™ is analyzing CT images of the brain

whereas NeuroQuant analyzes MRI images of the brain. Although CT CoPilot™ utilizes CT scans and NeuroQuant utilizes MRI scans, they both perform automated segmentation and quantification of segmental structures within the brain. Post-processing of the images with the Subject device (CT CoPilot™) and predicate device (NeuroQuant) use similar algorithms for segmentation and registration of scans to an Atlas as well as similar safety procedures to assess the quality of segmentation and registration accuracy.

CT CoPilot™ is substantially equivalent in performance, technology, and characteristics. The differences between the two devices do not raise any new questions of safety and effectiveness.