August 8, 2022

ClearPoint Neuro, Inc.
% John J. Smith
Partner
Hogan Lovells US LPP
555 Thirteenth St., NW
WASHINGTON DC 20004

Re: K213645
Trade/Device Name: ClearPoint Maestro™ Brain Model
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 16, 2022
Received: June 16, 2022

Dear John Smith:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Michael D. O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K213645

Device Name

ClearPoint Maestro™ Brain Model

Indications for Use *(Describe)*

ClearPoint Maestro™ Brain Model is intended for automatic labeling, visualization, volumetric and shape quantification of segmentable brain structures from a set of MR images. This software is intended to automate the process of identifying, labelling, and quantifying the volume and shape of brain structures visible in MRI images.

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

X 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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K213645

510(k) Summary

ClearPoint Neuro's ClearPoint Maestro™ Brain Model

Submitter

ClearPoint Neuro, Inc.
5 Musick
Irvine, CA 92618
Phone: (888) 287-9109
Contact Person: Megan Faulkenberry, VP, Quality and Regulatory

Date Prepared: August 5, 2022

Name of Device: ClearPoint Maestro™ Brain Model

Common or Usual Name: System, Image Processing, Radiological

Classification Name: Medical Image Management and Processing System (892.2050)

Regulatory Class: Class II

Product Code: QIH

Predicate Devices

CorTech Labs, Inc. - NeuroQuant (K061855)

Device Description

The ClearPoint Maestro™ Brain Model provides automated image processing of brain structures from T1-weighted MR images. Specifically, the device automates the manual process of identifying, labeling, and quantifying the volume and shape of subcortical and cortical structures to simplify the workflow for MRI segmentation.

The ClearPoint Maestro™ Brain Model consists of the following key functional modules.

- DICOM Read Module
- Segmentation Module
- Visualization Module
- Exporting Module

The segmented brain structures are color coded and overlayed onto the MR images or be displayed as 3-D triangular mesh representation. The viewing capabilities of the device also provides anatomic orientation labels (left, right, inferior, superior, anterior, posterior), image slice selection, standard image manipulation such as contrast adjustment, rotation, zoom, and the ability to adjust the transparency of the image overlay.

The output from ClearPoint Maestro™ Brain Model can also exported as a report in PDF format. The report also provides a comparison of segmented volume to normative values of brain structures based on reference data.

Intended Use / Indications for Use

ClearPoint Maestro™ Brain Model is intended for automatic labeling, visualization, volumetric and shape quantification of segmentable brain structures from a set of MR images. This software is intended to automate the process of identifying, labelling, and quantifying the volume and shape of brain structures visible in MRI images.

Comparison of Technological Characteristics with Predicate Device

Both ClearPoint Maestro™ Brain Model and NeuroQuant automate MR image post-processing to provide labeling, visualization, and volumetric quantification of brain structures. Both systems use as input clinical T1-weighted brain MR scans and automatically provide quantification of brain structures. The output results are provided in DICOM format and provide the segmented structures as a color-coded overlay onto the image series. The results can also be exported within a report as a PDF.

There are minor technological differences between the ClearPoint Maestro™ Brain Model and NeuroQuant. Notably, NeuroQuant performs automatic segmentation and quantification of brain structures using a probabilistic neuroanatomical atlas based on MR image intensity, while ClearPoint Maestro™ Brain Model uses shape-constrained segmentation of sub-cortical brain regions, the hemispheres, and the cerebellum, followed by voxel-wise tissue parcellation of the hemispheres and the cerebellum into tissue types. However, based on the assessment of device performance, these minor differences do not affect safety and effectiveness.

Both ClearPoint Maestro™ Brain Model and NeuroQuant are intended to be used by medical professionals such as radiologists, neurologists, and neuroradiologists as a tool to aid in the assessment and the simplification of the workflow for MR image segmentation.

Performance Data

The segmentation accuracy and reproducibility of ClearPoint Maestro™ Brain Model was assessed by comparing the device output to manually labeled data T1-weighted MRI data. The segmentation accuracy success was defined as Dice coefficient >0.7 and relative volume difference <0.3 between the device output and manually labeled data for the full population of the validation data. The reproducibility success criteria were defined as absolute volume differences <15% between segmentation performed on two repeated scans.

The means of computed Dice coefficients for 21 segmented brain structures in 101 subjects from the validation dataset were significantly greater than 70%, meeting the acceptance criteria. This result was observed in both the full population and in all subgroups. The only region with a mean Dice coefficient less than 70% was the third ventricle, which was attributed to variability in the manual labeling rather than device performance. This was further supported by the ClearPoint Maestro™ Brain Model reproducibility results, which showed that the device provided reproducible results while the manual labeling showed large variability.

The means of computed relative volume differences for 21 segmented brain structures in 101 subjects from the validation dataset were significantly less than 0.3, meeting the acceptance criteria. This result was observed in the full population and in all subgroups except one (18-25yo) where the left and right lateral ventricles were with higher means. That was again attributed to variability in the manual labeling rather than device performance.

In the reproducibility analysis, absolute volume differences using ClearPoint Maestro Brain Model 1.0 to segment the repeated scans in the 20Repeat data set were less than 10% for all segmented brain regions, including the third ventricle.

Machine learning derived outputs are the volumes of the gray and white matter in the cerebellum and the left and right cerebral hemispheres: Cerebellum GM, Cerebellum WM, L Cortical GM, and R Cortical GM, L Cortical WM, R Cortical WM. The training data was created by the three technical experts at Philips Research Hamburg. Validation was performed in 101 subjects from the validation dataset, which was completely independent from the training data created by Philips. All machine learning derived outputs met the acceptance criteria. Their Dice coefficient was greater than 70% and their mean relative volume difference was less than 0.3 in both the full population and in all subgroups.

Based on the bench testing performance, the ClearPoint Maestro™ Brain Model has a safety and effectiveness profile that is similar to the predicate device.

Conclusion

The ClearPoint Maestro™ Brain Model has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the ClearPoint Maestro™ Brain Model and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ClearPoint Maestro™ Brain Model is as safe and effective as NeuroQuant. Thus, the ClearPoint Maestro™ Brain Model is substantially equivalent.