November 19, 2021

CorTechs Labs, Inc.
% Kora Marinkovic
Director of Quality and Regulatory Affairs
5060 Shoreham Place, Suite 240
SAN DIEGO CA 92122

Re: K210831
Trade/Device Name: OnQ Neuro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: October 11, 2021
Received: October 15, 2021

Dear Kora Marinkovic:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K210831

Device Name
OnQ Neuro

Indications for Use *(Describe)*
OnQ Neuro is a fully automated post-processing medical device software intended for analyzing and evaluating neurological MR image data.
OnQ Neuro is intended to provide automatic segmentation, quantification, and reporting of derived image metrics.
OnQ Neuro is additionally intended to provide automatic fusion of derived parametric maps with anatomical MRI data.
OnQ Neuro is intended for use on brain tumors, which are known/confirmed to be pathologically diagnosed cancer.
OnQ Neuro is intended for comparison of derived image metrics from multiple time-points.
The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

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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510(k) Summary: OnQ Neuro

1. Submitter

Name	**CorTechs Labs, Inc.**
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Date Prepared	11/19/2021

2. Device

Device Trade Name	OnQ Neuro
Common Name	Medical Image Processing Software
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Description	Medical image management and processing system
Product Code	QIH
Classification Panel	Radiology

3. Predicate Devices

Primary Predicate Device

Device	Multi-Modality Tumor Tracking (MMTT)
510(k) Number	K162955
Manufacturer	Philips Medical Systems
Product Code	LLZ

4. Device Description

OnQ Neuro is a fully automated post-processing medical device software that is used by radiologists, oncologists, and other clinicians to assist with analysis and interpretation of neurological MR images. It accepts DICOM images using supported protocols and performs 1) automatic segmentation and volumetric quantification of brain tumors, which are known/confirmed to be pathologically diagnosed cancer, 2) automatic post-acquisition analysis of diffusion-weighted magnetic resonance imaging (DWI) data and optional automated fusion of derived image data with anatomical MR images, and 3) comparison of derived image metrics from multiple time-points.

Output of the software provides values as numerical volumes, and images of derived data as grayscale intensity maps and as graphical color overlays on top of the anatomical image. OnQ Neuro output is provided in standard DICOM format as image series and reports that can be displayed on most third-party commercial DICOM workstations.

The OnQ Neuro is a stand-alone medical device software package that is designed to be installed in the cloud or within a hospital's IT infrastructure on a server or PC-based workstation. Once installed and configured, the OnQ Neuro software automatically processes images sent from the originating system (MRI scanner or PACS). The software is configured at installation to receive input DICOM files from a network location, and output DICOM to a network destination.

The software is designed without the need for a user interface after installation. Any processing errors are reported either in the output series error report, or system log files.

OnQ Neuro software is intended to be used by trained personnel only and is to be installed by trained technical personnel.

Quantitative reports and derived image data sets are intended to be used as complementary information in the review of a case.

The OnQ Neuro software does not have any accessories or patient contacting components.

The OnQ application is intended to be used for the adult population only.

5. Indications for Use

OnQ Neuro is a fully automated post-processing medical device software intended for analyzing and evaluating neurological MR image data.
OnQ Neuro is intended to provide automatic segmentation, quantification, and reporting of derived image metrics.
OnQ Neuro is additionally intended to provide automatic fusion of derived parametric maps with anatomical MRI data.
OnQ Neuro is intended for use on brain tumors, which are known/confirmed to be pathologically diagnosed cancer.
OnQ Neuro is intended for comparison of derived image metrics from multiple time-points.
The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

6. Predicate Device

Philips Medical Systems' Multi-Modality Tumor Tracking (MMTT, K162955) market-cleared device is identified as the primary predicate device for the OnQ Neuro application.

	510(k) Number	Product Name	Submitter
Primary Predicate	K162955	Multi-Modality Tumor Tracking (MMTT)	Philips Medical Systems

The proposed OnQ Neuro application and its predicate device, MMTT (K162955), are substantially equivalent in regard to their general intended uses, intended users, clinical indications, and principle of operation. They have similar basic design and features.

7. Comparison to Predicate Device

Summary Comparison Table for the device (OnQ Neuro) and the predicate device (MMTT)

Feature	**OnQ Neuro**	**MMTT**: K162955 **(Predicate)**
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Product Code	LLZ	LLZ
Regulation Description	Picture archiving and communication system	Picture archiving and communication system
Regulation number	21 CFR 892.2050	21 CFR 892.2050
Intended Use	MR imaging data post processing software	MR imaging data post processing software
Intended users	Radiologists, oncologists	Radiologists, oncologists
Type of Imaging Scan	MRI	CT, MR PET/CT and SPECT/CT
Intended Body part	Neurological images	All body images
Support Longitudinal Analysis	Yes - performs comparison of derived image metrics from multiple time points	Yes
Support 2D and 3D anatomical sequences	Yes	Yes
Automatic image registration between series within a study	Yes	Yes
Segmentation editing tools	No	Yes

Tumor Segmentation Type	Fully-automated	Semi-Automated and manual
Findings management of identified tumors	Yes. Prior segmentation results are provided numerically.	Yes.
Quantitative Analysis of Regions-of-Interest	Yes. Including ROI Volumes, and histogram statistics of optional quantitative maps.	Yes. Including Volume, Min/Max/Mean
Reporting	Results displayed in tabular and graphical formats.	Results displayed in tabular and graphical formats.
DICOM Communication	Yes	Yes
Diffusion Analysis	Yes, including single and multi-compartment diffusion models.	No
Image Fusion	Automated fusion of segmentation results and parametric maps.	Automated fusion of segmentation results.
Safety	Display/measurement data can be viewed, accepted, or rejected by a physician.	Display/measurement data can be viewed, accepted, or rejected by a physician.
Environment for use	Hospital, Clinic, Imaging Center, Medical Offices	Hospital, Clinic, Medical Offices

Description of Similarities and Differences: OnQ Neuro and MMTT (Predicate)

Both applications, the OnQ Neuro and the MMTT (Predicate), 1) are post-processing software applications for analysis of MR imaging data; 2) have the ability to perform volumetric quantification of MR imaging data; 3) offer the ability to compare medical images and/or multiple time-points; 4) enable visualization of information that would otherwise have to be visually compared disjointedly; 5) have the ability to report derived imaging metrics; and 6) are intended for use on brain tumors, which are known/confirmed to be pathologically diagnosed cancer.

They differ in that: 1) The Intended Use of the MMTT application includes language regarding viewing and manipulation of images. Specifically, MMTT provides editing tools for manual and semi-manual tumor annotation and allows loading of multiple concurrent studies for temporal measurements. OnQ Neuro does not include a GUI, so it does not include the ability to manually annotate and manipulate images; 2) While MMTT utilizes a manual, user-dependent feature to outline regions of interest, the OnQ Neuro software provides similar segmentation functionality automatically (i.e., without user intervention); 3) The OnQ Neuro software performs automated analysis of diffusion-weighted images and returns an *Apparent Diffusion Coefficient* (ADC) map and an enhanced DWI map (the *Restricted Signal Map*) showing the restricted component of the water diffusion signal, which the MMTT application does not include; 4) The MMTT application provides multi-modality support for CT, MR PET/CT and SPECT/CT scans, which includes support for SUV calculation of PET scans. OnQ Neuro supports only MR scans; and 5) While both applications perform measurements of the ROIs, the MMTT application allows for measurements that support oncology response criteria; OnQ Neuro does not specifically support

oncology response criteria.

The CorTechs' OnQ Neuro and the identified Philips Medical Systems Multi-Modality Tumor Tracking (MMTT, K162955) are substantially equivalent in terms of indication for use, intended users, principle of operation and safety and/or effectiveness.

In conclusion, CorTechs believes that the proposed OnQ Neuro does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate device Multi-Modality Tumor Tracking (MMTT, K162955).

8. Performance and V&V Testing Summary

OnQ Neuro software application was tested in accordance with CorTechs verification and validation (V&V) processes. All product and engineering specifications were verified and validated. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

The V&V and performance data were provided in support of safety and effectiveness for the substantial equivalence determination.

Performance Testing Summary

Performance testing included protocols demonstrating accuracy of automated segmentation compared to manual radiologist segmentations. OnQ Neuro software performs automatic post-acquisition analysis of anatomical and diffusion-weighted MRI and coregistration, fusion, and quantification of supported regions. OnQ Neuro automatic segmentation performance is evaluated by comparing the software-derived segmentations to expert-labeled segmentations of brain tumors, which are known/confirmed to be pathologically diagnosed cancer. Comparisons to expert segmentations are quantified using the Dice similarity coefficient (extent of software-derived vs. ground truth overlap), and squared correlation coefficient (R^2) of segmented region of interest volumes. Acceptance criteria are set such that OnQ Neuro v1.1 model performance is consistent (95% percent performance) with expert rater manual segmentation performance and meets minimum clinically acceptable levels. The results of the segmentation performance testing on an independent test dataset demonstrate that OnQ Neuro v1.1.0 segments brain tumor ROIs with an accuracy that passed the product's acceptance criteria. Further, segmentation performance is consistent across scanner manufacturers, field strengths, tumor types, and patient sexes. We conclude that OnQ Neuro v1.1.0 brain tumor segmentation is sufficiently accurate to be used in clinical practice in accordance with the OnQ Neuro v1.1.0 Indications for Use.

V&V Testing Summary

OnQ Neuro tumor segmentation performance is additionally tested using three separate testing methods: 1) objective unit testing comparing the software-derived values to the known ground truth values, 2) system testing to verify that the Tumor Segmentation RGB Overlay and Tumor

Segmentation Report are correctly generated when compatible anatomical images are input to OnQ Neuro, and 3) clinical validation testing that the Tumor Segmentation RGB Overlay and Tumor Segmentation Report are correct, meet clinical expectations, and are safe and effective.

OnQ Neuro diffusion modeling performance is evaluated using three separate testing methods: 1) objective unit testing comparing the software-derived values using synthetic input data, with multiple levels of Rician noise, to the known ground truth values, 2) system testing to verify that the Restricted Signal Map and ADC map are correctly generated when compatible diffusion images are input to OnQ Neuro, and 3) clinical validation testing that the Restricted Signal Map and ADC map are correct, meet clinical expectations, and are safe and effective.

The test results in this 510(k) premarket notification demonstrate that the OnQ Neuro: 1) complies with the international and FDA-recognized consensus standards and FDA guidance documents, as listed on the CDRH Premarket Review Submission Cover Sheet Form, and 2) meets the acceptance criteria and is adequate for its intended use and specifications.

V&V activities required to establish performance and functionality of OnQ Neuro were performed. Testing performed demonstrated the OnQ Neuro meets all defined functionality requirements and performance claims.

9. Conclusions

The comparison between the two devices demonstrates that OnQ Neuro is as safe and as effective as its predicate, the Multi-Modality Tumor Tracking application (MMTT). Both OnQ Neuro and its predicate are substantially equivalent in regard to their general intended uses, intended users, and principle of operation. They have similar basic design, functions and technological characteristics. To address the technological differences the appropriate V&V and performance testing has been performed. The V&V testing demonstrates the safety and effectiveness of the device to meet its intended use and specifications. The performance testing shows that the device performs as well as gold standard - computer-aided expert manual segmentation.

By virtue of the physical characteristics and intended use, OnQ Neuro is substantially equivalent to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.