May 30, 2023

Omniscient Neurotechnology Pty Ltd (O8t)
% Jennifer Dixon
NASA Lead, QA/RA
Level 10, 580 George Street
Sydney, NSW 2000
AUSTRALIA

Re: K222359
Trade/Device Name: Quicktome Software Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 12, 2023
Received: May 15, 2023

Dear Jennifer Dixon:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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)*
K222359

Device Name
Quicktome Software Suite

Indications for Use *(Describe)*
The Quicktome Software Suite is composed of a set of modules intended for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, 3D visualization (MPR reconstructions and 3D volume rendering) and display of BOLD (blood oxygen level dependent) resting-state MRI scan studies.
Modules are available for image processing, atlas-assisted visualization and segmentation, resting state analysis and visualization, and target export creation and selection, where an output can be generated for use by a system capable of reading DICOM image sets.
Quicktome is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white-matter tracts based on constrained spherical deconvolution methods and for the use of said maps to select and create exports. Quicktome can generate motor, language, and vision resting state fMRI correlation maps using task-analogous seeds.
Typical users of Quicktome are medical professionals, including but not limited to surgeons, clinicians, and radiologists.

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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5.0 510(k) Summary

5.1 Submitter

Omniscient Neurotechnology Pty Ltd (o8t)
Level 10, 580 George Street
Sydney, NSW 2000
Australia

Contact Person: Jennifer Dixon

Date Prepared: May 24th, 2023

5.2 Device

Name of Device:	Quicktome Software Suite
Common or Usual Name:	Neurological Planning and Visualization Software
Classification:	Medical image management and processing system (21 CFR 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ

5.3 Predicate Device

StealthViz Advanced Planning Application with StealthDTI Package, K081512

This Predicate has not been subject to a design-related recall.

Reference Devices: Quicktome, K203518; Brainlab iPlan Cranial, K113732

5.4 Device Description

Quicktome is a software-only, cloud-deployed, image processing package which can be used to perform DICOM image viewing, image processing, and analysis.

Quicktome can receive (“import”) DICOM images from picture archiving and communication systems (PACS), acquired with MRI, including Diffusion Weighted Imaging (DWI) sequences, T1, T2, BOLD, and FLAIR images. Quicktome can also receive Resting State functional MRI (rs-fMRI) blood-oxygen-level-dependent (BOLD) datasets. Once received, Quicktome removes protected health information (PHI) and links the dataset to an encryption key, which is then used to relink the data back to the patient when the data is exported to hospital PACS or other DICOM device.

The software provides a workflow for a clinician to:

- Select an image for planning and visualization,
- Validate image quality,
- Explore the available anatomical regions, network templates, tractography bundles, and parcellations,
- Select regions of interest,

- Display resting state fMRI (BOLD) correlation maps using task-analogous seeds for Motor, Vision and Language networks, and
- Export black and white and color DICOMs for use in systems that can view DICOM images.

5.5 Indications for Use

The Quicktome Software Suite is composed of a set of modules intended for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, 3D visualization (MPR reconstructions and 3D volume rendering), and display of BOLD (blood oxygen level dependent) resting-state MRI scan studies.

Modules are available for image processing, atlas-assisted visualization and segmentation, , resting state analysis and visualization, and target export creation and selection, where an output can be generated for use by a system capable of reading DICOM image sets.

Quicktome is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white-matter tracts based on constrained spherical deconvolution methods and for the use of said maps to select and create exports. Quicktome can generate motor, language, and vision resting state fMRI correlation maps using task-analogous seeds.

Typical users of Quicktome are medical professionals, including but not limited to surgeons, clinicians and radiologists.

5.6 Comparison of Technological Characteristics with the Predicate Device

The Quicktome Software Suite is an updated version of a device which has previously been cleared (K203518).

In terms of core functionality, technology, and performance, both Subject and Predicate:

- Allow import and export of DICOM images to a hospital PACS.
- Contain a graphical user interface to conduct planning and visualization.
- Display MRI anatomical images, as well as tractography constructed from Diffusion Weighted Images, in 2D and 3D views.
- Register tractography and an atlas to the underlying anatomical images.
- Allow adding, removing, and editing of objects (including automatically segmented and manually defined regions of interest).
- Are delivered as software on an off-the-shelf hardware platform.

The above technological characteristics were established in K203518 as equivalent to the predicate device. Said characteristics are unchanged in the Subject device.

The following has been included in this submission:

- **BOLD (Blood-oxygen-level-dependent imaging) signal processing**: StealthViz processes task-based fMRI data which allows the user to prepare task-activated maps, whereas the Quicktome Software Suite allows the user to prepare task-analogous (for vision, motor and language tasks) correlation maps using resting-state fMRI data.

This difference was verified and validated and did not lead to any additional questions of safety or effectiveness. Comparison to the predicate device in conjunction with design verification and

validation activities described in this 510(k) submission support substantial equivalence of Quicktome.

5.7 Performance Data

Software verification and validation testing were conducted and documentation was provided as recommended by the Guidance for Industry and FDA Staff *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005).

The software was developed in compliance with the requirements of IEC 62304, IEC 62366, ISO 14971, and NEMA PS 3.1-3.20.

All verification and validation activities required per the verification and validation plan were performed using cloud-based deployment of the software in production-equivalent state.

Software Verification

- Testing was conducted on software units and modules. System verification was performed to confirm implementation of functional requirements.
- Cloud infrastructure verification was performed to ensure suitability of cloud components and services.
- Algorithm performance verification was conducted to ensure computations were sound.

Software Validation

- Summative usability evaluation and design validation were performed by representative users.
- Performance evaluations were conducted for the BOLD processing pipeline. Evaluations included protocols for motion and noise correction, skull stripping, co-registration of anatomical scans and BOLD series, physiological noise correction, and correlation matrix computation.
- The resting-state fMRI correlation maps generated by Quicktome were compared to task-based fMRI activation maps for a range of pre-specified seeds using analytical and expert clinician evaluation.
    - Analytical evaluation demonstrated that activation in a task-based activation map is represented within the bounds of a correlation map generated with resting-state data when using a range of pre-specified seeds and thresholds, supporting substantial equivalence of the two maps.
    - Clinicians rated the networks as comparable per the pre-specified acceptance criteria to task-based fMRI maps for the clinical intended uses of presurgical planning and post-surgical assessment.

5.8 Conclusion

The design verifications conducted support the conclusion that Quicktome performs as intended in the specified use conditions. Quicktome performs in a way that does not raise new questions of safety and effectiveness when compared to currently marketed devices.