Omniscient Neurotechnology Pty Ltd (o8t)
℅ Arie Henkin
Head, QA/RA
Level 10, 580 George Street
Sydney, NSW 2000
AUSTRALIA

March 9, 2021

Re: K203518
Trade/Device Name: Quicktome
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and ommunications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 11, 2021
Received: February 16, 2021

Dear Arie Henkin:

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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203518

Device Name
Quicktome

Indications for Use *(Describe)*
Quicktome is intended for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, and 3D visualization (MPR reconstructions and 3D volume rendering). Modules are available for image processing and atlas-assisted visualization and segmentation, 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.

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

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary

K203518

5.1 Submitter

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

Contact Person: Arie Henkin

Date Prepared: February 11, 2021

5.2 Device

Name of Device:	Quicktome
Common or Usual Name:	Neurosurgical Planning and Visualization Software
Classification:	Picture archiving and communications 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 Device: 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 retrieve DICOM images from picture archiving and communication systems (PACS), acquired with MRI, including Diffusion Weighted Imaging (DWI) sequences, T1, T2, and FLAIR images. Once retrieved, 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 the hospital PACS. Processing is performed on the anonymized dataset in the cloud. Clinicians are served the processed output for planning and visualization on their local machine.

The software provides a workflow for a clinician to:

- Select a patient case for planning and visualization,
- Confirm image quality,
- Explore anatomical regions, network templates, tractography bundles, and parcellations,
- Create and edit regions of interest, and
- Export objects of interest in DICOM format for use in systems that can view DICOM images.

5.5 Indications for Use

Quicktome is intended for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, and 3D visualization (MPR reconstructions and 3D volume rendering). Modules are available for image processing and atlas-assisted visualization and segmentation, 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.

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

5.6 Comparison of Technological Characteristics with the Predicate Device

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 differences between the Predicate and the Subject device are:

- The delivery platform: StealthViz is a Software-as-Medical-Device loaded onto off-the-shelf hardware, such that all processing occurs on the local machine, while the subject device performs processing in the cloud.
- The algorithm for modeling diffusion data and generating tractography: StealthViz generates ROI-based DTI tractography while the subject device generates whole-brain CSD tractography.
- The atlas model: StealthViz uses the Schaltenbrand-Wahren Atlas while the subject device uses the Glasser Atlas.

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.

Performance and comparison validations were performed to show equivalence of generated tractography and atlas method.

Comparisons to the Predicate device in conjunction with design verification and validation activities described in the 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.

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.

Software Validation

Summative usability evaluation and design validation were performed by representative users. Performance and comparison evaluations were performed by representative users on a dataset not used for development composed of normal and abnormal brains. Evaluations included protocols to demonstrate performance and equivalence of tractography bundle and anatomical region generation (including acceptable co-registration of bundles and regions with underlying anatomical scans), and evaluation of the algorithm's performance in slice motion filtration and skull stripping. A literature review was conducted for the clinical suitability and appropriate display of network templates.

5.8 Conclusion

The design verifications conducted support the conclusion that Quicktome performs as intended in the specified use conditions. The design validation, along with comparison and performance validation studies, support the conclusion that Quicktome performs comparably to the predicate device that is currently marketed for the same intended use.