TeraRecon, Inc
Michael Sosebee
Official Correspondent
4309 Emperor Blvd.
Durham, North Carolina 27703

August 12, 2022

Re: K220349
Trade/Device Name: TeraRecon Neuro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 28, 2022
Received: June 29, 2022

Dear Michael Sosebee:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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)*
K220349

Device Name
TeraRecon Neuro

Indications for Use *(Describe)*
The TeraRecon Neuro Algorithm is an algorithm for use by trained professionals, including but not limited to physicians, surgeons and medical clinicians.

The TeraRecon Neuro Algorithm is a standalone image processing software device that can be deployed as a Microsoft Windows executable on off-the-shelf hardware or as a containerized application (e.g., a Docker container) that runs on off-the-shelf hardware or on a cloud platform. Data and images are acquired via DICOM compliant imaging devices. DICOM results may be exported, combined with, or utilized by other DICOM-compliant systems and results.

The TeraRecon Neuro Algorithm provides analysis capabilities for functional, dynamic, and derived imaging datasets acquired with CT or MRI. It can be used for the analysis of dynamic brain perfusion image data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to brain tissue perfusion, vascular assessment, tissue blood volume, and other parametric maps with or without the ventricles included in the calculation. The algorithm also include volume reformat in various orientation, rotational MIP 3D batch while removing the skull. This "tumble view" allows qualitative review of vascular structure in direct correlation to the perfusion maps for comprehensive review.

The results of the TeraRecon Neuro Algorithm can be delivered to the end-user through image viewers such as TeraRecon's Aquarius Intuition system, TeraRecon's Eureka AI Results Explorer, TeraRecon's Eureka Clinical AI Platform, or other image viewing systems like PACS that can support DICOM results generated by the TeraRecon Neuro Algorithm.

The TeraRecon Neuro Algorithm results are designed for use by trained healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

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.

1 510(k) Summary

TeraRecon Neuro version 2.0.0
[in accordance with 21CFR 807.92]

1.1 Submitter

510(k) Sponsor:	TereRecon, Inc.
Address:	4309 Emperor Blvd., Durham, NC 27703, USA
Contact Person:	Michael Sosebee Senior Manager RAQA
Contact Information:	Email: msosebee@terarecon.com Phone: 704-651-6828
Date Summary Prepared:	10Feb2022

1.2 Subject Device

Proprietary (Trade) Name of Subject Device	TeraRecon Neuro
Model Number	2.0.0
Device Class	2
Common / Classification Name	System, Image Processing, Radiological
Product Code	LLZ
Regulation Number	892.2050
510(k) Number	K220349

1.3 Predicate Device

Proprietary (Trade) Name of Predicate Device	Neuro.AI Algorithm
Model Number	1.0.0
Device Class	2
Common / Classification Name	System, Image Processing, Radiological
Product Code	LLZ
Regulation Number	892.2050
510(k) Number	K200750

1.4 Device Description

The TeraRecon Neuro algorithm version 2.0.0 is a modification of the predicate device Neuro.AI Algorithm (K200750), which was a modification of the predicate device, Intuition-TDA, TVA, Parametric Mapping (which was cleared under K131447). The predicate device Intuition -TDA, TVA, Parametric Mapping is an optional module/workflow for the Intuition system (K121916). The TeraRecon Neuro algorithm is an image processing software device that can be deployed as a Microsoft Windows executable on off-the-shelf hardware or as a containerized application (e.g., Docker container) that runs on off-the-shelf hardware or on a cloud platform. The device has limited network connectivity or external medical support.

TeraRecon Neuro allows motion correction and processes, calculates and outputs brain perfusion analysis results for functional, dynamic, and derived imaging datasets acquired with CT or MRI. TeraRecon Neuro results are used for the analysis of dynamic brain perfusion image data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to brain tissue perfusion, vascular assessment and tissue blood volume.

Outputs include parametric map of measurements including time to peak (TTP), take off time (TOT), recirculation time (RT), mean transit time (MTT), blood volume (BV/CBV), blood flow (BF/CBF), time to maximum (Tmax) and penumbra/umbra maps that are derived from combinations of measurement parameters, such as mismatch maps and hypoperfusion maps with volumes and ratios, as well as 2D and 3D visualization of brain tissues and brain blood vessels (Note: Tmax, mismatch and hypoperfusion maps are only available for images of CT modality).

When TeraRecon Neuro results are used in external viewer devices such as TeraRecon's Intuition or Eureka medical devices, all the standard features offered by Intuition or Eureka are employed such as image manipulation tools like drawing the region of interest, manual or automatic segmentation of structures, tools that support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed by the software.

The TeraRecon Neuro algorithm outputs can be used by physicians to aid in the diagnosis and for clinical decision support including treatment planning and post treatment evaluation. The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by individuals that have been trained in the software's function, capabilities and limitations. The device is intended to provide supporting analytical tools to a physician, to speed decision-making and to improve communication, but the physician's judgment is paramount, and it is normal practice for physicians to validate theories and treatment decisions multiple ways before proceeding with a risky course of patient management.

1.5 Indications for Use

The TeraRecon Neuro algorithm is an algorithm for use by trained professionals, including but not limited to physicians, surgeons and medical clinicians.

The TeraRecon Neuro algorithm is a standalone image processing software device that can be deployed as a Microsoft Windows executable on off-the-shelf hardware or as a containerized application (e.g., a Docker container) that runs on off-the-shelf hardware or on a cloud platform. Data and images are acquired via DICOM compliant imaging devices. DICOM results may be exported, combined with, or utilized by other DICOM-compliant systems and results.

The TeraRecon Neuro algorithm provides analysis capabilities for functional, dynamic, and derived imaging datasets acquired with CT or MRI. It can be used for the analysis of dynamic brain perfusion image data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to brain tissue perfusion, vascular assessment, tissue blood volume, and other parametric maps with or without the ventricles included in the calculation. The algorithm also include volume reformat in various orientation, rotational MIP 3D batch while removing the skull. This “tumble view” allows qualitative review of vascular structure in direct correlation to the perfusion maps for comprehensive review.

The results of the TeraRecon Neuro algorithm can be delivered to the end-user through image viewers such as TeraRecon’s Aquarius Intuition system, TeraRecon’s Eureka AI Results Explorer, TeraRecon’s Eureka Clinical AI Platform, or other image viewing systems like PACS that can support DICOM results generated by the TeraRecon Neuro Algorithm.

The TeraRecon Neuro algorithm results are designed for use by trained healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

1.6 Summary of Technological Characteristics

The TeraRecon Neuro algorithm version 2.0.0 (K220349) is substantially equivalent to the predicate device, Neuro.AI Algorithm (K200750). It has the same basic technological characteristics as the predicate device. The main difference between the subject device and the predicate device is the addition of three perfusions maps Tmax, Hypoperfusion and Mismatch along with improvements made to the quality of existing perfusions maps in version 1.0.0 BV, BF, MTT, TOT, TTP and RT. The subject and predicate devices both allow motion correction and process, calculate and output brain perfusion analysis results for functional, dynamic and derived imaging datasets acquired with CT or MRI. The subject and predicate device results are used for visualization and analysis of dynamic brain perfusion image data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to brain tissue perfusion, vascular assessment and tissue blood volume.

Outputs include parametric map of measurements including time to peak (TTP), take off time (TOT), recirculation time (RT), mean transit time (MTT), blood volume (BV/CBV), blood flow (BF/CBF), time to maximum (Tmax) and penumbra/umbra maps that are derived from combinations of measurement parameters, such as mismatch maps and hypoperfusion maps with volumes and ratios, as well as 2D and 3D visualization of brain tissues and brain blood vessels.

TeraRecon Neuro can be used by physicians to aid in the diagnosis and for clinical decision support including treatment planning and post treatment evaluation.

Both the subject and predicate devices are interoperable or compatible with CT and MR scanners, 3rd party hospital systems such as PACS, and the TeraRecon Intuition platform. Both devices are standalone software packages, the results of which can be consumed by and viewed by TeraRecon's Eureka AI Results Explorer or by other image viewing systems that can support the results generated by the TeraRecon Neuro algorithm.

The differences in technological characteristics do not raise any new or different questions of safety of effectiveness. Software verification and validation testing validates that the TeraRecon Neuro algorithm is as safe and effective as the predicate device in order to support a determination of substantial equivalence.

See the table below for a description of the technological similarities and differences among the subject and predicate device.

Table 1: Technological Characteristics Comparison

Functionality	Subject Device TeraRecon Neuro version 2.0.0 (TBD)	Predicate Device Neuro.AI Algorithm version 1.0.0 (K200750)	Reference Device (Used in Qualitative Assessment) FastStroke, CT Perfusion 4D (K193289)	Reference Device (Used in Qualitative Assessment) iSchemaView RAPID (K182130)
Areas of Use	Same as predicate device	Radiology and could also include other clinical specialty areas such as emergency, neurology, surgery and more	Not specified in K193289's 510(k) summary.	Hospital LAN, inside the Hospital Firewall To be used by trained professionals. Radiological data network.
Modality Support	Same as predicate device	Vendor-neutral - CT, MR and other volumetric imaging modalities. Images are exposed over time.	CT	CT and MRI
Body Part	Same as predicate device	Head – entire brain or from lower edge of the base of nucleus to upper edge of the ventricles.	Head and Body	Not specified in K182130's 510(k) summary
DICOM® formats	Same as predicate device	NEMA PS 3.1 – 3.20 (2016)	DICOM 3.0 image compatibility	NEMA PS 3.1 – 3.20 (2016)

Functionality	Subject Device TeraRecon Neuro version 2.0.0 (TBD)	Predicate Device Neuro.AI Algorithm version 1.0.0 (K200750)	Reference Device (Used in Qualitative Assessment) FastStroke, CT Perfusion 4D (K193289)	Reference Device (Used in Qualitative Assessment) iSchemaView RAPID (K182130)
Operating System	Same as predicate device	Microsoft Windows® executable on off the shelf hardware and CentOS (Interoperability)	Not specified in K193289's 510(k) summary	The software runs on a standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Linux-based server

Functionality	Subject Device TeraRecon Neuro version 2.0.0 (TBD)	Predicate Device Neuro.AI Algorithm version 1.0.0 (K200750)	Reference Device (Used in Qualitative Assessment) FastStroke, CT Perfusion 4D (K193289)	Reference Device (Used in Qualitative Assessment) iSchemaView RAPID (K182130)
Key Functionality/ Feature and Region-of-Interest (ROI) Markers	Same as predicate device	• Automatic arterial and venous input function selection • Ventricle subtraction	CT perfusion 4D is an image analysis software package, which allows the user to produce dynamic image data and to generate information with regards to changes in image intensity over time. It supports the analysis of CT Perfusion images (in the head and body) after the intravenous injection of contrast, and calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability).	The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion - weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Functionality	Subject Device TeraRecon Neuro version 2.0.0 (TBD)	Predicate Device Neuro.AI Algorithm version 1.0.0 (K200750)	Reference Device (Used in Qualitative Assessment) FastStroke, CT Perfusion 4D (K193289)	Reference Device (Used in Qualitative Assessment) iSchemaView RAPID (K182130)
Perfusion measurements and color maps	• Same as predicate device and • Time to Maximum (Tmax) • Hypoperfusion maps and volumes • Mismatch maps (penumbra/umbra maps that are derived from combinations of measurement parameters) and related volumes and ratios	• Time to peak (or Time to Minimum) • Take off time (or Maximum Slope of Increase) • Recirculation time (RT) • Mean transit time (MTT) • Blood volume (BV/CBV) • Blood flow (BF/CBF) • User configurable settings	• Blood Flow • Blood Volume • Mean Transit Time • Capillary Permeability • Time to Maximum	• Blood Flow • Blood Volume • Mean Transit Time • Time to Maximum
Graph Displays	Same as predicate device	Artery and Vein Fitted and Raw curves – time/activity	Not specified in K193289's 510(k) summary	Not specified in K182130's 510(k) summary
Export Capability	• Same as predicate device and • Artery Intensity Profile	DICOM files	Not specified in K193289's 510(k) summary	Not specified in K182130's 510(k) summary
Methods for Mathematical Modeling	Same as predicate device	SVD	Not specified in K193289's 510(k) summary	Not specified in K182130's 510(k) summary
Arterial and Venous Input Function Selection	Same as predicate device	Automatic	Not specified in K193289's 510(k) summary	Arterial input function (AIF) and Venous output function (VOF)

Functionality	Subject Device TeraRecon Neuro version 2.0.0 (TBD)	Predicate Device Neuro.AI Algorithm version 1.0.0 (K200750)	Reference Device (Used in Qualitative Assessment) FastStroke, CT Perfusion 4D (K193289)	Reference Device (Used in Qualitative Assessment) iSchemaView RAPID (K182130)
Containerization / dockerization of algorithm that enables interoperability with 3rd party results including viewing such results	Same as predicate device	• Neuro.AI Algorithm is hosted on the Eureka platform within its own docker. The algorithm is triggered based on input data and generates result which will be delivered to third party system. • CT and MR Scanners • 3rd party hospital systems such as a PACS server, EMR or other • TeraRecon Intuition • Visualization system • Other image viewing systems that can support results generated by the Neuro.AI Algorithm • Notification systems	The configuration of NeuroPackage enables the user to open a single application, FastStroke, which provides them access to both the updated CT Perfusion 4D and FastStroke applications. The capabilities in CT Perfusion 4D and FastStroke can be offered independently.	RAPID is available in the following configurations: • Standard RAPID, which is installed directly on a customer's Linux-based server and integrated with medical image processing software such as commercial PACS. • Virtual RAPID, wherein the user accesses RAPID online and uses it to process DICOM images otherwise available on his/her computer.
Ventricle Subtraction	Same as predicate device	Setting allows software to calculate maps with or without ventricle included.	Ventricle Segmentation	Not specified in K182130's 510(k) summary

1.7 Performance Data

Safety and performance of the TeraRecon Neuro algorithm have been verified and validated through software testing, quantitative phantom testing and qualitative clinical user evaluation. Software development and testing were performed in accordance with IEC 62304:2006/AI:2015, Medical Device Software – Software life cycle processes, utilizing a risk-based testing methodology. Risk has been evaluated in accordance with ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices. During software testing, all pre-defined acceptance criteria for the Neuro.AI Algorithm were met and all software test cases passed. The same verification and validation methodology, risk assessment and acceptance criterion were used for predicate device.

To execute our clinical user evaluation TeraRecon worked with our evaluator Dr. Robert Falk, MD whom was presented with comparison maps generated by the subject device, the predicate device and two additional reference devices GE Medical Systems FastStroke CT Perfusion 4D (K193289) and ISchemaView RAPID (K182130). The evaluator was asked to confirm through qualitative assessment that the generated maps of TeraRecon Neuro are at least 85% substantially equivalent or better than the predicate and reference devices.

Additionally, we performed a quantitative evaluation of Tmax measurements in comparison to the two reference devices. Considering the ground truth as the average Tmax measurement of the two reference devices for a given ROI, we calculated absolute error and absolute percent error for the subject device compared to ground truth. Acceptance criteria was defined as subject device limit of agreement for both metrics less than or equal than the limit of agreement of each predicate device compared to the ground truth.

The results of the software testing and clinical user evaluation validate that the TeraRecon Neuro device meets its qualified requirements, performs as intended, and is as safe and effective as the predicate device. No new or different questions of safety or efficacy have been raised as a result of the verification and validation process.

1.8 Conclusion

The TeraRecon Neuro algorithm is as safe and effective as the predicate device, Neuro.AI Algorithm. The indications for use of the subject device falls within the scope of that for the predicate device. Many of the technological characteristics are the same for the subject and predicate devices. Differences in the technological characteristics between the subject and predicate devices have been addressed through software verification and validation testing and do not raise any new of different questions of safety and effectiveness.

All risk were analyzed, and there are no new risks or modified risks that could result in significant harm which are not effectively mitigated in the predicate device. The analysis above supports a determination of Substantial Equivalence of the TeraRecon Neuro algorithm to the predicate device in terms of safety, efficacy, and performance.