TeraRecon, Inc.
% Mr. Patrick Willhite
Director, Quality Assurance and Regulatory Affairs
4309 Emperor Blvd., Suite 310
DURHAM NC 27703

November 6, 2020

Re: K200750
Trade/Device Name: Neuro.AI Algorithm
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 26, 2020
Received: October 28, 2020

Dear Mr. Willhite:

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.
Diretor
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)*
K200750

Device Name
Neuro.AI Algorithm

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

The Neuro.AI 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 Neuro.AI algorithm provides analysis capabilities for static, 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 and tissue blood volume and other parametric maps with or without the ventricles included in the calculation. The algorithm also includes volume reformat in various orientations, 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 Neuro.AI Algorithm can be delivered to the end-user through image viewers such as TeraRecon's Aquarius iNtuition system, TeraRecon's Northstar AI Results Explorer, or other image viewing systems like PACS that can support DICOM results generated by Neuro.AI.

The Neuro.AI 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.

510(K) SUMMARY

[In accordance with 21CFR 807.92]

1. SUBMITTER

510(k) Sponsor:	TereRecon, Inc.
Address:	4309 Emperor Blvd., Suite 310 Durham, NC 27703, USA
Contact Person:	Patrick Willhite Director of Quality Assurance and Regulatory Affairs
Contact Information:	Email: pwillhite@terarecon.com Phone: 919.670.1539 Facsimile: 650.372.1101
Date Summary Prepared:	10/30/2020

2. DEVICE

Proprietary (Trade) Name:	Neuro.AI Algorithm ("Neuro.AI")
Common Name:	Medical Imaging System
Classification:	§ 892.2050, Picture Archiving and Communication System.
Product Codes:	LLZ – System, Image Processing, Radiological

3. PREDICATE DEVICE

Predicate Device	iNtuition-TDA, TVA and Parametric Mapping (K131447)
Reference Device	iNtuition system (K121916)

4. DEVICE DESCRIPTION

The Neuro.AI Algorithm is a modification of the predicate device, iNtuition-TDA, TVA, Parametric Mapping which was cleared under K131447. The predicate device is an optional module/workflow for the iNtuition system (K121916). The Neuro.AI 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., Docker container) that runs on off-the-shelf hardware or on a cloud platform. The device has limited network connectivity or external medical support.

The Neuro.AI Algorithm allows motion correction and processes, calculates and outputs brain perfusion analysis results for static, functional, dynamic and derived imaging datasets acquired with CT or MRI. Neuro.AI 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 displayed in rotational Maximum Intensity Projection (MIP) called the tumble view, and tissue blood volume and other parametric maps with or without brain ventricles included in the calculation.

Outputs include text and parametric map displays 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), classification maps, reformatted images and rotational MIPs for 2D and 3D visualization of brain tissues and blood vessels, and for correlation to the perfusion maps.

The results of the Neuro.AI Algorithm can be delivered to the end-user through image viewers such as TeraRecon's iNtuition system, TeraRecon's Northstar AI Results Explorer ("Northstar"), or other third-party image viewing systems like PACS that can display the DICOM results generated by Neuro.AI. The Neuro.AI output does not depend on the viewing system's capabilities as the results are self-contained and the only interface is through DICOM.

When the Neuro.AI Algorithm results are used on iNtuition, all the standard features offered by iNtuition 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 Neuro.AI algorithm can be used by physicians to aid in the diagnosis. 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.

5. INDICATIONS FOR USE

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

The Neuro.AI 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 Neuro.AI Algorithm provides analysis capabilities for static, 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 and tissue blood volume and other parametric maps with or without the ventricles included in the calculation. The algorithm also includes volume reformat in various orientations, 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 Neuro.AI Algorithm can be delivered to the end-user through image viewers such as TeraRecon's Aquarius iNtuition system, TeraRecon's Northstar AI Results Explorer, or other image viewing systems like PACS that can support DICOM results generated by Neuro.AI.

The Neuro.AI 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.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Neuro.AI Algorithm is substantially equivalent to the predicate device, iNtuition-TDA, TVA, Parametric Mapping (K131447). It has the same intended use and the same basic technological characteristics as the predicate device. The main difference between the subject and predicate device is the standalone nature of the subject device.

Both the subject and predicate device allow motion correction and processes, calculates and outputs brain perfusion analysis results for static, functional, dynamic and derived imaging datasets acquired with CT or MRI. The 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 displayed in rotational Maximum Intensity Projection (MIP) called the tumble view, and tissue blood volume and other parametric maps. The subject device can also display maps with or without brain ventricles included like the reference device, iNtuition system (K121916). The reference device includes segmentation functionality where the segmentation can be displayed or hidden for any part of the body, including brain ventricles.

Outputs include text and parametric map displays 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), classification maps, reformatted images and rotational MIPs for 2D and 3D visualization of brain tissues and blood vessels, and for correlation to the perfusion maps.

Both the subject and predicate devices are interoperable or compatible with CT and MR scanners, third-party hospital systems such as PACS, and the iNtuition platform. The subject device is a standalone software device, the results of which can also be consumed by and viewed by TeraRecon's Northstar AI Results Explorer via EnvoyAI as the algorithm hosting platform or by other third-party image viewing systems that can display the DICOM results generated by the Neuro.AI Algorithm.

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

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

TABLE 1: TECHNOLOGICAL CHARACTERISTICS COMPARISON

	Subject Device Neuro.AI Algorithm (TBD)	**Predicate Device iNtuition-TDA, TVA, Parametric Mapping (K131447)**	**Reference Device iNtuition system (K121916)**
Areas of Use	Same and other trained clinical users	Radiology	Radiology
Modality Type	Same	Vendor-neutral - CT, MR and other volumetric imaging modalities. Images are exposed over time.	Vendor-neutral - CT, MR, Nuc, PET, Angio, US/Echo, SPECT, CR/DR Review
DICOM® formats	Same and DICOM 3.x	Yes, supports DICOM 3.0	Yes, supports DICOM 3.0
Operating System	Same and CentOS (Interoperability)	Microsoft Windows® executable on off-the-shelf hardware	Microsoft Windows® executable on off-the-shelf hardware
Body Part	Same	Head – entire brain or from lower edge of the base of nucleus to upper edge of the ventricles.	Head and other regions and organs within the body
Key Functionality/ Features	• 2D, 3D and 4D viewing, multi-phase series support, zoom, pan, window level, rotate, cine and display layouts and templates • ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations • Arterial and venous input function selection, automatic and manual • Ventricle segmentation	• 2D, 3D and 4D viewing, multi-phase series support, zoom, pan, window level, rotate, cine and display layouts and templates • ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations • Arterial and venous input function selection, automatic and manual	• 2D, 3D and 4D viewing, multi-phase series support, zoom, pan, window level, rotate, cine and display layouts and templates • ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations • Arterial and venous input function selection, automatic and manual • Ventricle segmentation
Ventricle Segmentation	Setting allows software to display maps with or without brain ventricles included	This device is a module of iNtuition. When used with iNtuition, the segmentation tools can be applied to any part of the body, including brain ventricles.	Editing and segmentation tools are provided including freehand crop, cut, dynamic region grow, bone removal tools, rib cage removal, table removal tools, and tools to provide an initial selection of bone or air-filled vessels (e.g. lung or colon) for removal or improvement. Any segmentation can be displayed or hidden and this is applicable for any

	Subject Device Neuro.AI Algorithm (TBD)	Predicate Device iNtuition-TDA, TVA, Parametric Mapping (K131447)	Reference Device iNtuition system (K121916)
			part of the body, including brain ventricles.
Perfusion measurements and color maps	• Same	• Time to Peak (TTP) • Take off Time (TOT or Maximum Slope of Increase) • Recirculation Time (RT) • Mean Transit Time (MTT) • Blood Volume (BV/CBV) • Blood Flow (BF/CBF) • Perfusion Maps	• Time to Peak (TTP) • Take off Time (TOT or Maximum Slope of Increase) • Recirculation Time (RT) • Mean Transit Time (MTT) • Blood Volume (BV/CBV) • Blood Flow (BF/CBF) • Perfusion Maps
Graph Displays	Same	Artery and Vein Fitted and Raw curves – time/activity	Artery and Vein Fitted and Raw curves – time/activity
Export Format	Same	DICOM format	DICOM format plus JPEG, BMP, AVI, Word
Methods for Mathematical Modeling	Same	SVD	SVD
Arterial and Venous Input Function Selection	Same	Automatic and manual	Automatic and manual
Interoperability/ Compatibility	• CT and MR Scanners • Third-party hospital systems such as a PACS server, EMR or other • iNtuition Advanced Visualization system • Algorithm dockerization using Docker™ hosted in TeraRecon's EnvoyAI platform and viewed by	• CT and MR Scanners • Third-party hospital systems such as PACS server, EMR or other • iNtuition advanced visualization system	• CT and MR Scanners plus other imaging modalities • Third-party hospital systems such as PACS server, EMR or other

	Subject Device Neuro.AI Algorithm (TBD)	Predicate Device iNtuition-TDA, TVA, Parametric Mapping (K131447)	Reference Device iNtuition system (K121916)
	Northstar AI Results Explorer • Other image viewing systems that can support DICOM results generated by the Neuro.AI Algorithm • Notification systems		

7. PERFORMANCE DATA

Safety and performance of the Neuro.AI Algorithm have been verified and validated through software testing and performance evaluation. Software development and testing were performed in accordance with IEC 62304:2006/A1:2015, 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.

The results of the software and performance testing validate that the Neuro.AI Algorithm 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.

8. CONCLUSION

The Neuro.AI Algorithm is as safe and effective as the predicate device, iNtuition-TDA, TVA, Parametric Mapping module. The Neuro.AI Algorithm has the same intended use and the indications for use fall within the scope of that for the predicate device. Many of the technological characteristics are the same for the subject and predicate devices. Any differences in technological characteristics between the subject and predicate devices have been addressed through software verification/validation testing and performance testing and do not raise any new or different questions of safety or effectiveness. Additionally, the differences in technological characteristics have been compared to a reference device which is currently legally marketed in the United States.

All risks were analyzed and no new risks, changes to existing risks, or new risk controls were identified as a result of the Neuro.AI Algorithm. The testing results and analysis above support a determination of Substantial Equivalence of the Neuro.AI Algorithm to the predicate device in terms of safety, efficacy, and performance.