September 29, 2023

Terran Biosciences, Inc.
% Kay Fuller
Principal Regulatory & Clinical Research Consultant
Medical Device Regulatory Solutions, LLC
230 Collingwood Dr., Suite 260
Ann Arbor, Michigan 48103

Re: K230187
Trade/Device Name: Terran NM-101
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LLZ
Dated: August 26, 2023
Received: August 29, 2023

Dear Kay Fuller:

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 (the 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 available 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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)*
K230187

Device Name
Terran NM-101

Indications for Use *(Describe)*

Terran NM-101 is a post-processing software medical device intended for use in visualization of the brain in older adults between the age of 51 to 83 years. Terran NM-101 analyzes input data acquired from Siemens 3T MR imaging systems, using a specified protocol (i.e., Turbo Spin Echo, TSE). Terran NM-101 can generate qualitative parametric maps from non-contrast T1-weighted image MR acquisition.

Terran NM-101 is also intended for automatic labeling, visualization, volumetric quantification and contrast quantification of segmentable brain tissues from a set of Siemens 3T acquired MR images. Brain tissue characterization and volumes of neuromelanin associated signal contrasts are determined based on analysis of qualitative parametric maps.

When interpreted by a neuroradiologist, Terran NM-101 images can provide information useful in determining neuromelanin association as an adjunct to diagnosis.

Terran NM-101 must always be used in combination with a T1-weighted image MR acquisition.

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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510(k) SUMMARY

Terran Biosciences, Inc.
Terran NM-101

September 19, 2023

The following summary is provided pursuant to Section 513 (I) (3) (A) of the Federal Food Drug and Cosmetic Act:

1. GENERAL INFORMATION

Submitter Information: Terran Biosciences, Inc.
2457 Collins Ave., Suite 504
Miami Beach, FL 33140

Contact Information: Kay Fuller, RAC
Principal Regulatory & Clinical Research Consultant
Medical Device Regulatory Solutions, LLC
734-846-7852

2. DEVICE INFORMATION

Device Name: Terran NM-101

Proprietary Name: Terran NM-101

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name: Magnetic Resonance Diagnostic Device

Classification Code: LNH, LLZ

Regulation Number: 21 CFR §892.1000

3. PREDICATE DEVICE(S)

The Terran NM-101 is similar to the primary predicate device SyMRI cleared for US commercialization via K191036, on 6/13/2019 and predicate device NeuroQuant cleared for US commercialization via K170981, on 9/7/2017.

4. DEVICE DESCRIPTION

Terran NM-101 is a fully automated post-acquisition software as a medical device (SaMD) that measures neuromelanin associated contrast to noise ratio (CNR) signal in the substantia nigra (SN) and locus coeruleus (LC) regions of non-contrast brain magnetic resonance imaging (MRI) images from Siemens 3 tesla (3T) MRI scanners. Terran NM-101 can generate qualitative parametric maps from non-contrast T1-weighted image MR acquisition.

5. INDICATIONS FOR USE

Terran NM-101 is a post-processing software medical device intended for use in visualization of the brain in older adults between the age of 51 to 83 years. Terran NM-101 analyzes input data acquired from Siemens 3T MR imaging systems, using a specified protocol (i.e., Turbo Spin Echo, TSE). Terran NM-101 can generate qualitative parametric maps from non-contrast T1-weighted image MR acquisition.

Terran NM-101 is also intended for automatic labeling, visualization, volumetric quantification and contrast quantification of segmentable brain tissues from a set of Siemens 3T acquired MR images. Brain tissue characterization and volumes of neuromelanin associated signal contrasts are determined based on analysis of qualitative parametric maps. When interpreted by a neuroradiologist, Terran NM-101 images can provide information useful in determining neuromelanin association as an adjunct to diagnosis.

Terran NM-101 must always be used in combination with a T1-weighted image MR acquisition**.**

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Terran NM-101 fundamental technological characteristics are similar to those of the predicate devices as described herein, and as described in the following table.

Feature Comparison Criteria	Subject Device Terran NM-101 K230187	Primary Predicate Device A K191036 SyMRI	Subject Device SE to K191036?	Predicate Device B K170981 NeuroQuant	Subject Device SE to K173224?
21 CFR Reg #, Product Code & Classification	21 CFR §892.1000 21 CFR §892.2050 LNH / LLZ Class II	21 CFR §892.1000 LNH Class II	Yes	21 CFR §892.2050 LLLZ Class II	Yes
Regulation Name	Magnetic resonance diagnostic device; Picture archiving and communication system	Magnetic resonance diagnostic device	Yes	Picture archiving and communications system	Yes
Prescription Device Rx Only	Yes	Yes	Yes	Yes	Yes
Indications for Use	Terran NM-101 is a post-processing software medical device intended for use in visualization of the brain in older adults between the age of 51 to 83 years. Terran NM-101 analyzes input data acquired from Siemens 3T MR imaging systems, using a specified protocol (i.e., Turbo Spin Echo, TSE). Terran NM-101 can generate qualitative parametric maps from non-contrast T1-weighted image MR acquisition. Terran NM-101 is also intended for automatic labeling, visualization, volumetric quantification and contrast quantification of segmentable brain tissues from a set of Siemens 3T acquired MR images. Brain tissue characterization and volumes of neuromelanin associated signal contrasts are determined based on analysis of qualitative parametric maps. When interpreted by a neuroradiologist, Terran NM-101 images can provide information useful in determining neuromelanin association as an adjunct to diagnosis. Terran NM-101 must always be used in combination with a T1-weighted image MR acquisition.	SyMRI is a post-processing software medical device intended for use in visualization of the brain. SyMRI analyzes input data from MR imaging systems. SyMRI utilizes data from a multi-delay, multi-echo acquisition (MDME) to generate parametric maps of R1, R2 relaxation rates, and proton density (PD). SyMRI can generate multiple image contrasts from the parametric maps. SyMRI enables post-acquisition image contrast adjustment. SyMRI is indicated for head imaging. SyMRI is also intended for automatic labeling, visualization and volumetric quantification of segmentable brain tissues from a set of MR images. Brain tissue volumes are determined based on modeling of parametric maps from MDME. When interpreted by a trained physician, SyMRI images can provide information useful in determining diagnosis. SyMRI should always be used in combination with at least one other MR acquisition (e.g., T2-FLAIR).	Yes	NeuroQuant is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric measurements may be compared to reference percentile data.	Yes
Intended Users	Qualified Radiologist	Qualified Radiologist	Yes	Qualified Radiologist	Yes

Feature Comparison Criteria	Subject Device Terran NM-101 K230187	Primary Predicate Device A K191036 SyMRI	Subject Device SE to K191036?	Predicate Device B K170981 NeuroQuant	Subject Device SE to K173224?
Type of Imaging Scans	MRI	MRI	Yes	MRI	Yes
Target Organ/System	MR Brain	MR Brain	Yes	MR Brain	Yes
Handle Multiple Studies	Yes	Yes	Yes	Yes	Yes
Field Strength	No : 1.5T Yes : 3.0T	No: 1.5T Yes: 3.0T	Yes	Yes: 1.5T No: 3.0T	Yes
Mode	3D	3D	Yes	3D	Yes
Plane	Sagittal	Sagittal	Yes	Sagittal	Yes
Contrast Enhancement	T1	T1	Yes	T1	Yes
Sequence	MPRAGE	MPRAGE	Yes	MPRAGE	Yes
Slice Thickness	1.8 mm	Unknown	No	1.2 mm	Yes
TR	600 ms	650 ms	Yes	2300 ms	Yes
TE	10 ms	10 ms	Yes	Minimum	Yes
TI	~	~	Yes	900 ms	Yes
Acquisition Time	8 mins	6 mins	Yes	5-7 mins	Yes
Flip Angle	120°	Unknown	No	9°	Yes
Filter	Non	Non	Yes	Non	Yes
Data Source	Siemens 3T MRI scanner: T1 MRI scans acquired with specified protocols (i.e., TSE) Terran NM-101 Supports DICOM format as input	MRI scanner: 3D T1 MRI scans acquired with specified protocols (i.e., MDME – GE MAGiC, Philips SyntAc; Siemens 3 T TSE_MDME) SyMRI Supports DICOM format as input	Yes	MRI scanner: 3D T1 MRI scans acquired with specified protocols NeuroQuant Supports DICOM format as input	Yes
Operating System	Cloud-Based, Windows, Linux	Network Based Option, Windows, macOS	Yes	Cloud-Based, Windows, macOS, Linux	Yes
Output	Supports DICOM format as output of results that can be displayed on DICOM workstations and PACS. Automatic labeling, visualization, volumetric quantification and contrast quantification of segmentable brain tissues from a set of Siemens 3T acquired MR images. Brain tissue characterization and volumes of neuromelanin associated signal contrasts are determined based on analysis of qualitative parametric maps. Includes segmented color overlays and parametric map reports. When interpreted by a neuroradiologist, Terran NM-101 images can provide information useful in determining neuromelanin association as an adjunct to diagnosis.	Supports DICOM format as output of results that can be displayed on DICOM workstations and PACS. Automatic labeling, visualization and volumetric quantification of segmentable brain tissues from a set of MR images. Brain tissue volumes are determined based on modeling of parametric maps from MDME. Includes segmented color overlays and parametric map reports. When interpreted by a trained physician, SyMRI images can provide information useful in determining diagnosis.	Yes	Supports DICOM format as output of results that can be displayed on DICOM workstations and PACS. Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Provides volumetric measurements of brain structures and lesions Includes segmented color overlays and morphometric reports. Automatically compares results to reference percentile data and to prior scans when available.	Yes
Safety	Automated quality control functions: - Complete input set check - Scan protocol verification - Brain alignment check - NM associated CNR value check - PHI check - Cybersecurity threat assessment (CTA) attestation Results must be reviewed by a neuroradiologist – adjunctive use indication	Automated quality control functions: None published Results must be reviewed by a trained physician	Yes	Automated quality control functions: -Tissue contrast check - Scan protocol verification - Atlas alignment check Results must be reviewed by a trained physician	Yes
Sterility	N/A	N/A	N/A	N/A	N/A
Biocompatibility	N/A	N/A	N/A	N/A	N/A
Electrical Safety	N/A	N/A	N/A	N/A	N/A
Thermal Safety	N/A	N/A	N/A	N/A	N/A
Energy Used/Delivered	N/A	N/A	N/A	N/A	N/A
Chemical Safety	N/A	N/A	N/A	N/A	N/A
Radiation Safety	N/A	N/A	N/A	N/A	N/A

7. NON-CLINICAL TESTING SUMMARY

The following design control, risk management and quality assurance methodologies were utilized to develop Terran NM-101:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on Unit Level (Verification)
- Integration Testing (System Verification)
- Performance Testing (V&V)
- Safety Testing (V&V)
- Simulated Use Testing (Validation)

Software documentation for Moderate Level of Concern software per the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005, is also included in this premarket notification submission. Terran NM-101 was tested in accordance with the company's verification and validation procedures.

All predefined acceptance criteria for the engineering (pre-clinical) performance testing were met. The results from the pre-clinical testing performed on Terran NM-101 produced results consistently according to its intended use.

8. CLINICAL TESTING SUMMARY

The subject device of this premarket notification, Terran NM-101, did not require clinical studies to support substantial equivalence to the predicate devices.

The results of the clinical performance reviews of the Terran NM-101 reports by neuroradiologists demonstrate that the Terran NM-101 clinical user needs and intended use requirements were fulfilled and all acceptance criteria were met.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The subject device and the primary predicate device are substantially equivalent, with respect to intended use, instructions for use, design features, technological characteristics, manufacturing methods, performance criteria, special controls, and safety and effectiveness. The subject device is substantially equivalent to the primary predicate device (K191036) noted herein.

10. CONCLUSION

The non-clinical and clinical reviews contained herein, demonstrates that Terran NM-101 performs according to its intended use. Terran Biosciences, Inc. considers the Terran NM-101 (subject device) to be substantially equivalent to the legally marketed primary predicate device noted herein, and is safe and effective for its labeled intended use.