NovaSignal Corporation
% Carrene Plummer
Senior Regulatory Affairs Manager
2440 S. Sepulveda Blvd., Ste 115
LOS ANGELES CA 90064

Re: K213279 March 2, 2022
Trade/Device Name: NovaGuide 2 Intelligent Ultrasound
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, OQQ
Dated: January 24, 2022
Received: January 26, 2022

Dear Carrene Plummer:

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
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213279

Device Name
NovaGuide 2 Intelligent Ultrasound

Indications for Use *(Describe)*
NovaGuide 2 Intelligent Ultrasound is a medical ultrasound system intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream. The system assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows.

NovaGuide 2 Intelligent Ultrasound is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

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 0MB number."*

7 510(K) SUMMARY K213279

7.1 Submitter Information

Submitter: NovaSignal Corporation

Address: 2440 South Sepulveda Blvd., Ste. 115, Los Angeles, CA 90064

Establishment Registration Number: 3013368530

Contact Person: Raajdeep (Raaj) Venkatesan

Phone: (323) 252-4762

Facsimile: (310) 819-1676

Email: raaj@novasignal.com

Date Prepared: October 7, 2021

7.2 Name of Device and Classification

Trade Name: NovaGuide 2 Intelligent Ultrasound

Common Name: NovaGuide 2

Model Numbers:

NSC-NVGSYS2 – NovaGuide 2 Intelligent Ultrasound
NSC-TCDNG2 – NovaGuide 2 Traditional

Classification Name: Ultrasonic pulsed doppler imaging system (21 CFR 892.1550); Transducer, Ultrasonic, Diagnostic (21 CFR 892.1570); Diagnostic Ultrasonic Transducer, Robotic (21 CFR 892.1570)

Product Codes: IYN, ITX, OQQ

7.3 Predicate Device

Primary Predicate Device: NeuralBot, NovaSignal Corporation (K180455)

Reference Device: Lucid M1 Transcranial Doppler Ultrasound System, NovaSignal Corporation (K160442)

7.4 Device Description

7.4.1 NovaGuide 2 Configuration

NovaGuide 2 is a mobile, non-invasive, non-ionizing radiation transcranial Doppler (TCD) ultrasound system. It is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream. NovaGuide 2 is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

NovaGuide 2 is a cart-mounted system for use in hospitals or clinics. The system is comprised of a computer, Doppler Robotics Unit (DRU), probe pods, patient headmount unit (PHU) and two reusable, non-sterile 2-MHz transducers that can be operated in either robotic or manual modes. When used in robotic mode, the operator is guided in positioning the two transducers, one on each side of the patient's head. The transducers are positioned using robotic actuators that adjust the translational and angular positions using TCD signal search algorithms, which assists the operator in monitoring the blood flow velocity of the vessels via the patient's temporal acoustic windows. Visualization and detection of emboli occur through High-Intensity Transient Signals (HITS) in the display of the TCD blood flow.

7.4.2 NovaGuide 2 Traditional Configuration

NovaGuide 2 Traditional is an adjunctive portable, non-invasive, non-ionizing radiation, point-of-care TCD ultrasound system. It is designed to measure and display cerebral blood flow velocities and detect emboli within the arteries of the head and neck. NovaGuide 2 Traditional Configuration does not contain the robotic Patient Headmount Unit; therefore, it can only be used in manual mode using the supplied 2MHz handheld transducers.

7.4.3 Software Description

7.4.3.1 NovaGuide 2 Software

The all-in-one computer hosts the NovaGuide 2 application software. The software processes TCD data and provides Graphical User Interface (GUI), and, for NovaGuide 2, setup and procedural and algorithmic search commands to the PHU via the DRU.

7.4.3.2 NovaGuide View™ Software Accessory

NovaGuide View is an optional and supplemental accessory to NovaSignal medical ultrasound systems. NovaGuide View is intended to transfer, store, convert formats, enhance, and display transcranial Doppler (TCD) ultrasound exam data and results, originating from NovaSignal ultrasound systems. In addition, it allows qualified healthcare personnel to add and approve interpretations of exam data and remotely view live streaming of exams.

7.5 Indications for Use

NovaGuide 2 Intelligent Ultrasound is a medical ultrasound system intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream. The system assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows.

NovaGuide 2 Intelligent Ultrasound is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

7.6 Intended Use

NovaGuide 2 Intelligent Ultrasound is intended to be used during diagnostic exams and surgical interventions as an adjunct to the standard clinical practices for measuring and displaying cerebral

blood flow velocity within the major conducting arteries of the head and neck. Cerebral blood flow velocity within these arteries is visualized using non-invasive pulsed transcranial Doppler ultrasound (TCD). This includes, but is not limited to, insonation of the middle, anterior and posterior cerebral arteries via the temporal windows, the vertebral and basilar arteries via the foramen magnum, and the ophthalmic arteries and internal carotid artery siphons via the patient's transorbital windows.

TCD is a common tool for the visualization of cerebral blood flow velocity and the detection of emboli which present as High-Intensity Transient Signals (HITS) in the display of the TCD blood flow.

7.7 Predicate Device Comparison

7.7.1 Device Comparison Similarities

Table 7-1 Predicate Device Comparison Similarities

Technological Characteristic	**NovaGuide 2 Intelligent Ultrasound** **SUBMISSION DEVICE**	**Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) – Lucid TCD** **(Reference Device) K160442**	**NeuralBot when connected to the Lucid M1 System - NovaBot** **(Primary Predicate) K180445**
Product Code, Class	IYN, ITX, OQQ Class II	IYN, ITX Class II	IYN, ITX, OQQ Class II
Indications for Use	NovaGuide 2 Intelligent Ultrasound is a medical ultrasound system intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the bloodstream. NovaGuide 2 Intelligent Ultrasound is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.	The Lucid M1 System is a medical ultrasound system intended for use as an adjunct to the standard clinical practices for measuring and displaying cerebral blood flow velocity within the major conducting arteries and veins of the head and neck. Additionally, The Lucid M1 System measures the occurrence of transient emboli signals within the blood stream. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.	The NeuralBot when used with Lucid M1 System is a medical ultrasound device which assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows. It is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the blood stream. The NeuralBot is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.
Energy Used/ Delivered	Ultrasound Energy	Ultrasound Energy	Ultrasound Energy
Design	1. Base Ultrasound Unit (touch screen display, integrated PC Board, TCD ultrasound driver sub-system)	1. Base Ultrasound Unit (touch screen display, integrated PC Board, TCD ultrasound driver sub-system)	Not Applicable to this System

Technological Characteristic	NovaGuide 2 Intelligent Ultrasound SUBMISSION DEVICE	Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) – Lucid TCD (Reference Device) K160442	NeuralBot when connected to the Lucid M1 System - NovaBot (Primary Predicate) K180445
	2. Reusable, non-sterile 2-MHz handheld transducer or headset with 2 reusable, non-sterile 2-MHz monitoring transducers 3. Software/firmware 4. Algorithm	2. Reusable, non-sterile 2-MHz handheld transducer or headset with 2 reusable, non-sterile 2-MHz monitoring transducers 3. Software/firmware 4. Algorithm	
Mechanism of Action	Doppler Ultrasound with the following modes: Unilateral, Bilateral, Multichannel, Monitoring, M-mode, Modified M-mode	Doppler Ultrasound with the following modes: Unilateral, Bilateral, Multichannel, Monitoring, M-mode, Modified M-mode	Doppler Ultrasound with the following modes: Unilateral, Bilateral, Multichannel, Monitoring, M-mode
Performance	Sample Volume: 2 to 12mm in 1mm steps Depth: 23 to 151mm Power %: 0 to 100% where 100% represents $I_{spta.3}$ upper-tolerance limit 720 mW/cm^2	Sample Volume: 2 to 12mm in 1mm steps Depth: 23 to 151mm Power %: 0 to 100% where 100% represents $I_{spta.3}$ upper-tolerance limit 720 mW/cm^2	Sample Volume: 10mm Depth: 45 to 60 mm Power %: 0 to 100% where 100% represents $I_{spta.3}$ upper-tolerance limit 575 mW/cm^2
Acoustic Output	NovaGuide 2 global maximum derated ISPTA is designed to be <720mW/cm2. NovaGuide 2 global maximum MI is designed to be < 1.0. The design of NovaGuide 2 will exceed a TIC (Cranial Thermal Index) of 1.0. The maximum TIC for the NovaGuide 2 is 2.5.	The Lucid M1 System global maximum derated ISPTA is designed to be <720mW/cm2. The Lucid M1 System global maximum MI is designed to be < 1.0. The design of Lucid M1 System will exceed a TIC (Cranial Thermal Index) of 1.0. The maximum TIC for the Lucid M1 System is 2.5.	The NeuralBot when connected to the Lucid M1 System has a global maximum derated ISPTA <720 mW/cm^2. The NeuralBot when connected to the Lucid M1 System has a global maximum MI < 1.0. The NeuralBot when connected to the Lucid M1 System will exceed a TIC (Cranial Thermal Index) of 1.0. The maximum TIC for the NeuralBot when connected to the Lucid M1 System is 2.5.
Clinical Measurements	• Maximum Velocity • Mean Velocity • Minimum Velocity • Pulsatility Index • Cerebrovascular Reactivity • Embolus Count	• Maximum Velocity • Mean Velocity • Minimum Velocity • Pulsatility Index • Cerebrovascular Reactivity • Embolus Count	• Maximum Velocity • Mean Velocity • Minimum Velocity • Pulsatility Index • Cerebrovascular Reactivity • Embolus Count
Track	Track 3	Track 3	Track 3
Patient-Contact Materials (Probes)	Transducer Front Face: Luran HD-20 (BASF) Transducer Body: Tecason P (Ensigner) Registration Dots Adhesive Tape: 3M-1509 Foam, Head Cradle: ZHB110G Cosmetic Foam Foam, Forehead Clamp: ZHB110G Cosmetic Foam	Transducer Front Face: Luran HD-20 (BASF) Transducer Body: Tecason P (Ensigner)	Transducer Front Face: Luran HD-20 (BASF) Transducer Body: Tecason P (Ensigner) Registration Dots Adhesive Tape: 3M-1509 Foam, Head Cradle: ZHB110G Cosmetic Foam Foam, Forehead Clamp: ZHB110G Cosmetic Foam

Technological Characteristic	NovaGuide 2 Intelligent Ultrasound SUBMISSION DEVICE	Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) – Lucid TCD (Reference Device) K160442	NeuralBot when connected to the Lucid M1 System - NovaBot (Primary Predicate) K180445
	Probe Pod Cover: Linear Low-Density Polyethylene		Probe Pod Cover: Linear Low-Density Polyethylene
Mains Input	100 to 240 VAC 50 to 60 Hz	100 to 240 VAC 50 to 60 Hz	100 to 240 VAC 50 to 60 Hz
Rechargeable Battery	Lithium Ion (TCD Driver) Lithium Ion (All in One Computer)	Lithium Ion (TCD Driver) Lithium Ion Polymer (Tablet)	Not Applicable to this System
Labeling	• Electrical Hazard Warnings • Non-temporal window scanning precaution (on-screen caution) • Not intended for fetal use warning • ALARA caution • Physician order caution • Supplemental TIC	• Electrical Hazard Warnings • Non-temporal window scanning precaution (on-screen caution) • Not intended for fetal use warning • ALARA caution • Physician order caution • Supplemental TIC	• Electrical Hazard Warnings • Non-temporal window scanning precaution (on-screen caution) • Not intended for fetal use warning • ALARA caution • Physician order caution • Supplemental TIC
Head Frame	Bilateral probes adjusted manually and/or automatically	Not Applicable to this System	Bilateral probes adjusted manually and/or automatically
Accessories	• Single-use patient contact materials provided in the NovaKit 2 Exam Pack (pack of 10) • Remote Control accessory	Remote Control accessory	Single-use patient contact materials supplied in a service pack
Transducers	2MHz PW 16mm hand - held transducers 2MHz PW 16mm monitoring transducers	2MHz PW 16mm hand - held transducers 2MHz PW 16mm monitoring transducers	Not Applicable to this System
Transducer Frequency	2 MHz	Not Applicable to this System	2 MHz
Transducer Frequency Spectrum	FFT 256	Not Applicable to this System	FFT 256
Frequency Ranges	2 MHz	Not Applicable to this System	2 MHz
Depth Measurement	45 to 60 mm	Not Applicable to this System	45 to 60 mm
Axis of Movement	X, Y, Z	Not Applicable to this System	X, Y, Z
Probe Angle Adjustment	Automatic	Not Applicable to this System	Automatic

Table 7-2 Predicate Device Comparison Differences

Technological Characteristic	**NovaGuide 2 Intelligent Ultrasound** **SUBMISSION DEVICE**	**Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) – Lucid TCD** **(Reference Device) K160442**	**NeuralBot when connected to the Lucid M1 System - NovaBot** **(Primary Predicate) K180445**
Laser	Class 1M laser to assist in head alignment	Not Applicable to this System	Not Applicable to this System
Graphical User Interface/ Computer	All-In-One computer	Medical tablet touchscreen with separate computer	2 medical tablet touchscreens (1 for Lucid M1 System, 1 for NeuralBot), and 2 separate computers (1 for Lucid M1 System, 1 for NeuralBot)
Accessories	NovaGuide View software accessory for remote viewing of patient results	Not Applicable to this System	Not Applicable to this System
VasoMotor Reactivity (VMR) Index	Calculation and display of VMR post exam following user selection of one of three options: • VMR • VMR with Hyperventilation • BMI	Not Applicable to this System	Not Applicable to this System
Shunt Grade Assist	Shower Region of Interest detection for Shunt Grade Assist to aid in detection of embolic events in Bubble exams	Not Applicable to this System	Not Applicable to this System
Emboli Finder	Enhanced emboli detection capability during Emboli exams	Original emboli detection capability during Emboli exams	Not Applicable to this System

7.8 Summary of Performance Testing

7.8.1 Nonclinical Testing

NovaGuide 2 performance was established through nonclinical testing conducted either externally by a qualified facility or internally by NovaSignal Corp. Assessment of basic safety and essential performance of ultrasonic diagnostic equipment occurred in accordance with IEC 60601-2-37. For evaluation of acoustic output, an Acoustic Power and Intensity measurement system (API) was used to measure acoustic power output while the NovaGuide 2 DRU and transducer operated in PW-Mode and at settings that produced maximum power output. The system generated passing results. Acoustic temperature was also evaluated per IEC 60601-2-37 in simulated use and still air conditions. NovaGuide 2 temperature rise for both conditions remained within limits, producing passing results.

Functional testing was also performed for signal search, depth and velocity, ALARA precaution messaging and controls, VMR Index, Shunt Grade Assist, and enhanced Emboli Finder. Step-by-step execution of each parameter was confirmed during simulated use operation. Expected outcomes were obtained for each parameter.

NovaGuide 2 safety and effectiveness was confirmed as evidenced by passing results obtained for all nonclinical testing. See Section 20 for nonclinical testing.

7.8.2 Biocompatibility Testing

NovaGuide 2 components are intended to contact intact skin for limited duration (≤ 24 hour). None of the materials in NovaGuide 2 differ from those existing and described in 510(k)s for the primary predicate device (NeuralBot, K180445) and the reference device (Lucid M1 System, K160442). Therefore, a table of summary biocompatibility evaluation information is provided in Section 17.

7.8.3 Electromagnetic Compatibility and Electrical Safety

NovaGuide 2 underwent equivalent Electromagnetic Compatibility (EMC) and electrical safety testing as did the predicate device. NovaGuide 2 complies with IEC 60601-1 and IEC 60601-1-2. See Section 19.

7.8.4 Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation is provided as recommended by FDA's guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered to have a "moderate" level of concern, since failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. See Sections 18.12 and 18.27 for NovaGuide 2 and NovaGuide View software verification and validation respectively.

7.8.5 Clinical Testing

Nonclinical testing was considered appropriate to confirm safety and effectiveness of NovaGuide 2; therefore, clinical testing was not performed.

7.9 Conclusion

The documentation provided demonstrates that:

- NovaGuide 2 Intelligent Ultrasound is substantially equivalent to the primary predicate device.
- There are no new questions of safety and effectiveness concerning NovaGuide 2 Intelligent Ultrasound.
- NovaGuide 2 Intelligent Ultrasound is designed to be as safe and effective as the primary predicate device.
- NovaGuide 2 Intelligent Ultrasound is designed to perform as well as the primary predicate device.

Accordingly, NovaGuide 2 Intelligent Ultrasound is believed to be substantially equivalent to the primary predicate device of the same type, which is lawfully distributed in interstate commerce in the United States.