DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Neural Analytics, Inc.
% Mr. Javad Seyedzadeh
Regulatory and Quality Advisor
2440 S. Sepulveda Blvd. Suite 115
LOS ANGELES CA 90064

October 21, 2016

Re: K160442
Trade/Device Name: Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) with 2 MHz Transducers
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX
Dated: September 23, 2016
Received: September 26, 2016

Dear Mr. Seyedzadeh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160442

Device Name
Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) with 2 MHz Transducers

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Indications for Use Form

System: Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic			N				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments: Items indicated as a new indication "N" for the Lucid M1 System are previously cleared by the FDA for the predicate devices.

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Indications for Use Form

System: Lucid M1 System
Transducer: 40-00008 Handheld 2 Mhz Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic			N				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments: Items indicated as a new indication "N" for the Lucid M1 System are previously cleared by the FDA for the predicate devices.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Indications for Use Form

System: Lucid M1 System
Transducer: 40-00009 Monitoring 2 Mhz Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic			N				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments: Items indicated as a new indication "N" for the Lucid M1 System are previously cleared by the FDA for the predicate devices.

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

Lucid M1 Transcranial Doppler Ultrasound System with 2-MHz Transducer

Date Prepared	February 10, 2016
Manufacturer	Neural Analytics, Inc. 2440 South Sepulveda Blvd, Suite 115 Los Angeles, CA 90064 *Phone:* (310) 819-1676 *Facsimile:* (310) 819-1676 *Internal Contact: Jay Yonemoto* *Email:* Jay@neuralanalytics.com
Official Correspondent	Javad Seyedzadeh Regulatory and Quality Advisor Neural Analytics, Inc. (914) 473-1678 javad@neuralanalytics.com
Common Name	Transcranial Doppler (TCD) Ultrasound System 2 MHz Ultrasound Transducer
Trade Name	Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) with 2 MHz Transducers
Model Number(s)	M1 (Lucid M1 System) 40-00008 (handheld 2 MHz transducer) 40-00009 (monitoring 2 MHz transducer)
Federal Regulation Number	21 CFR 892.1550 21 CFR 892.1570
Product Codes	IYN, ITX
Class	Class II Device

Predicate Device	K002533 Spencer Technologies, Inc. TCD 100 M, Transcranial Doppler Ultrasound System, CFR 892.1550, IYN Transducer PWD 13, Diagnostic Ultrasound Transducer; CFR 892.1570, ITX
Performance Standards	There are no required performance standards under the Federal Food, Drug and Cosmetic Act. Voluntary standards to which we will conform include: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-2-37, IEC 62133 (TCD Driver rechargeable battery) & UL 2504 (Tablet rechargeable battery).
Special Controls	There are no special controls as a special report is no longer required. The guidance referenced is "*Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*" dated September 9, 2008.

Device Description

The Lucid M1 System is an adjunctive, portable, non-invasive, non-ionizing radiation, point-of-care transcranial Doppler (TCD) diagnostic ultrasound system. It is designed to non-invasively measure and display cerebral blood flow velocity over the head and neck with a reusable, non-sterile 2-MHz hand-held probe. It can also be used bilaterally to monitor the blood flow velocity of the vessels insonated via the temporal window of the head with a headset with two reusable, non-sterile 2-MHz monitoring transducers. The system can also provide an emboli count for emboli detection.

Indications for Use

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.

Technological Characteristics Compared to Predicate Device

Technological Characteristic	Neural Analytics Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System)	Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533)
Product Code, Class	IYN, ITX Class II	IYN, ITX Class II
Indications for Use	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 TCD 100M transcranial Doppler ultrasound system is intended for use as a diagnostic ultrasound fluid flow analysis system: 1. For the measurement of cerebral artery blood velocities to determine the presence-of-hemodynamically significant deviations from normal values 2. To assess arterial cerebral blood flow for the occurrence of micro-embolic signals. Vessels intended for observation include, but are not limited to, the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral and basilar arteries via the foramen magnum, and the ophthalmic artery and intracranial internal carotid artery via the eye. The TCD 100M is intended for use during: Diagnostic exams Surgical interventions 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

Technological Characteristic	Neural Analytics Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System)	Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533)
Design	1. Base Ultrasound Unit (touch screen display, integrated PC Board, TCD ultrasound driver sub-system) 2. Reusable, non-sterile 2-MHz handheld probe or headset with two reusable, non-sterile 2-MHz monitoring transducers 3. Software/firmware 4. Algorithm	1. Base Ultrasound Unit (single board PC, master and slave Doppler boards, transducer detector circuit, flat panel display, keyboard, mouse, remote control keypad, audio output, hard disk, parallel port) 2. Reusable, non-sterile 2-MHz handheld probe or headset with 2 reusable, non-sterile 2-MHz monitoring probes 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
Accessories	2MHz PW 16mm hand held probes 2MHz PW 16mm monitoring probes	2Mhz PW 16mm hand held probes 2Mhz PW 16mm monitoring probes
Performance	Sample Volume: 2 to 12mm in 1mm steps Depth: 23 to 151mm Power% 0 to 100% where 100% represents Ispta.3 upper-tolerance limit 720 mW/cm^2	Similar information is provided by the predicate device
Acoustic Output	The Lucid M1 System global maximum derated ISPTA is designed to be <720mW/cm^2. 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.	Similar information is provided by the predicate device
Clinical Measurements	• Maximum Velocity • Mean Velocity • Minimum Velocity • Pulsatility Index • Cerebrovascular Reactivity • Embolus Count	• Peak • Diastolic velocity • Mean • PI • Delta Percent • Embolus Count
Track	Track 3	Track 1

Technological Characteristic	Neural Analytics Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System)	Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533)
Patient-Contact Materials (Transducers)	Transducer Front Face: Luran HD-20 (BASF) Transducer Body: Tecason P (Ensigner)	Transducer Front Face: Luran HD-20 (BASF) Transducer Body: Tecason P (Ensigner)
Mains Input	100 to 240 VAC 50 to 60 Hz	100 to 240 VAC 50 to 60 Hz
Rechargeable Battery	Lithium Ion (TCD Driver) Lithium Polymer (Tablet)	None
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

There are no unique features compared to the predicate device in principles of operation, specifications, performance, safety, and effectiveness.

Substantial Equivalence Discussion

The Lucid M1 System is substantially equivalent to the Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533) based on indications for use and comparison of the functional capabilities. Both of the devices are intended to provide a diagnostic ultrasound fluid flow analysis. Features common to all systems include:

- Transcranial Doppler ultrasound systems used for fluid flow analysis
- Monitor the cerebral arteries via the temporal windows
- Utilize two transducers which are attached via a headset for cephalic monitoring
- Use substantially equivalent operating modes
- Measure equivalent hemodynamic indices
- Have equivalent monitoring functions
- Display velocity spectrum and M-Mode
- Manufactured with materials that have been evaluated and found to be safe for the intended use of the device
- Have patient contact surfaces are manufactured from the same materials

- Manufactured to meet applicable physical, mechanical, and electrical safety requirements

The Lucid M1 System is substantially equivalent to the Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533). This is based on the comparison of the indications for use and comparison of the functional capabilities. Both of the devices are intended to provide a diagnostic ultrasound fluid flow analysis.

Device	Indications For Use	Comparison
Lucid M1 System	The Lucid M1 System is an adjunctive, portable, non-invasive, non-ionizing radiation, point-of-care transcranial Doppler (TCD) diagnostic ultrasound system. It is designed to non-invasively measure and display cerebral blood flow velocity over the head and neck with a reusable, non-sterile 2-MHz hand-held probe. It also used bilaterally to monitor the blood flow velocity of the vessels insonated via the temporal window of the head with a headset with two reusable, non-sterile 2-MHz monitoring transducers. The system can also provide an emboli count for emboli detection.	**Equivalent** to Predicate
TCD 100 M (K002533)	The TCD 100M is a computer based ultrasound system intended for transcranial Doppler (TCD), with a single type of pulse wave Doppler transducer that can be used free-hand (or mounted in a head frame for longer term monitoring). This comprises a Track 1 device with output exceeding cephalic limits and maximum Thermal Index Cranial included in the labeling (user manual). An M-mode image is used to help position the sample gate for Doppler signal, and for detection of embolic signals. The m-mode image does not represent a new insonation mode but rather is an additional display of information from the conventional pulsed Doppler signal.	

The minor differences (discussed below) between the Lucid M1 System and the Spencer Technologies TCD 100 M Transcranial Doppler Ultrasound System (K002533) do not raise new questions of safety or effectiveness. These differences are discussed as follows:

Performance:
The Lucid M1 System, uses a sample length of 2 to 12mm with a depth of 23 to 151mm. The sample length specified in the Lucid M1 System limits the selection to lengths that are commonly used. Similar information is provided by the predicate device (K002533).

Acoustic Output:
The Lucid M1 System has a global maximum derated ISPTA of 675mW/cm^2 which is less than 720mW/cm^2. The Lucid M1 System has a maximum Cranial Thermal Index (TIC) of 2.5. The user is kept informed of the current TIC value because it is presented on the Lucid M1 System display. Similar information is provided by the predicate device (K002533).

Rechargeable Battery:
The Lucid M1 System utilizes rechargeable batteries to allow the user to perform exams disconnected from the mains outlet (AC wall socket). The system allows a single channel TCD exam for a cumulative time of at least 1 hour. The rechargeable batteries in the Lucid M1 System will be compliant with the IEC 62133 (First and Second Edition Rechargeable Nickel or Lithium) and UL 2054 (Alkaline Cell or Lithium/Alkaline Packs) standards.

The TCD 100 M (K002533) does not have rechargeable battery. This is a user convenience feature that does not impact the operation of the unit.

Modified M-Mode:
In addition to the traditional M-mode found on the TCD 100M, the Lucid M1 System utilizes a modified M-mode display which is a presentation of the standard M-mode display information in a signal strength vs depth format. Using the Modified M-mode display, the operator can quickly acquire the spectrogram signal and therefore perform a faster exam. Using this feature, they can visualize the M-mode signal strength along the horizontal axis thereby allowing them to set the depth of the sample gate. The operator simply aligns the depth setting using the highest signal strength peak.

Automated Cerebrovascular Reactivity calculations:

Cerebrovascular Reactivity calculations are currently performed using a hand calculator and reading the measurements from the display. The Automated Cerebrovascular Reactivity feature avoids this manual operation by recommending a minimum velocity, maximum velocity and mean velocity and automatically generates a CVR calculation. The operator has an option to manually re-select the locations of the minimum, maximum, and mean velocity estimates in accordance to standard clinical practice.

The TCD 100M does not have this feature.

General Safety and Effectiveness and Performance Data

The Lucid M1 System is equivalent to currently distributed transcranial Doppler ultrasound systems with 2 MHz transducers. Maximum acoustic output levels for the Lucid M1 System will be below pre-amendment levels for acoustic intensity for this application, and for Mechanical Index for all applications. On-screen cautions will indicate appropriate power levels prior to the user beginning an exam. Power levels will be displayed at all times during scanning, and a standard spectrum display will be shown.

The design of the Lucid M1 System is being developed in accordance with the approved design plan and the requirements of 21 CFR Part 820. Quality management system procedures include, but are not limited to, risk analysis, requirement reviews, design reviews, verification and validation, performance testing, and safety testing.

Clinical Testing

The Lucid M1 System does not require clinical testing to show substantial equivalence to its predicate device in safety and effectiveness.

Summary of Non-Clinical Testing and Reliance on Standards

The Lucid M1 System is evaluated for acoustic output, biocompatibility, and accuracy, as well as thermal, electrical, electromagnetic, and mechanical safety. Non-clinical testing to support thermal, mechanical, electromagnetic, and mechanical safety is conducted per the FDA *Guidance Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,* using applicable sections of the following voluntary standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-37:2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- NEMA Standards Publication UD 2-2004(R2009) Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3
- NEMA Standards Publication UD 3-2004(R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 2
- IEC 60601-1-6: 2010 Medical electrical equipment – Part 1-6: General Requirements For Safety – Collateral Standard: Usability
- IEC 62133: 2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- UL 2054: 2004 Standard for Household and Commercial Batteries
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

Determination of Substantial Equivalence

The Lucid M1 System is determined to be substantially equivalent to devices of the same type that are currently lawfully distributed in interstate commerce in the United States with regard to intended use, modes, clinical measurements, acoustical power output, head fixation devices, safety and effectiveness.

Neural Analytics' Lucid M1 System and Spencer Technologies' TCD 100M are both transcranial Doppler ultrasound flow systems with monitoring functions. Both systems

monitor the cerebral arteries via the temporal windows and allow the user to examine the anterior and posterior cerebral arteries via the temporal windows, the vertebral and basal arteries via the foramen magnum, and the ophthalmic and intracranial internal carotid arteries via the eye.

Both systems have equivalent modes and use pulsed wave Doppler (PWD) and use color M-mode for location of the vessel of interest. Additionally, both devices:

- Are transcranial Doppler ultrasound systems used for fluid flow analysis
- Monitor the cerebral arteries via the temporal windows
- Utilize two transducers which are attached via a headset for cephalic monitoring
- Use substantially equivalent operating modes
- Measure equivalent hemodynamic indices
- Have equivalent monitoring functions
- Display velocity spectrum and M-Mode
- Are manufactured with materials that have been evaluated and found to be safe for the intended use of the device
- Have patient contact surfaces are manufactured from the same materials
- Are manufactured to meet applicable physical, mechanical, and electrical safety requirements

Conclusion

The documentation provided demonstrates that:

- The Lucid M1 System and transducers are substantially equivalent to the predicate devices.
- There are no new questions of safety and effectiveness concerning the Lucid M1 System and transducers.
- The Lucid M1 System is designed to be at least as safe and effective as the predicate devices.
- The Lucid M1 System is designed to perform as well as the predicate devices.

Accordingly, the Lucid M1 System is believed to be substantially equivalent to a predicate device of the same type which is lawfully distributed in interstate commerce in the United States.