March 8, 2018

HeadSense Medical Inc.
% Kit Cariquitan
Chief Regulatory Officer
Experien Group, LLC
224 Airport Parkway
Suite 250
San Jose, California 95110

Re: K172892
Trade/Device Name: Neuro Assessment System NAS-1000
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: QBE
Dated: September 21, 2017
Received: September 22, 2017

Dear Kit Cariquitan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172892

Device Name
Neuro Assessment System NAS-1000

Indications for Use *(Describe)*
The NAS-1000 System is a medical acoustic system intended as an adjunct to standard clinical practice for use in non-invasively monitoring, detecting, recording and displaying acoustic signals in the brain. It is used for any subject undergoing a physical examination and intended only for medical assessment purposes in a clinic or hospital.

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.

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## 510(k) Notification K172892

### GENERAL INFORMATION [807.92(a)(1)]

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**Date Prepared: February 5, 2018**

### DEVICE INFORMATION [807.92(a)(2)]

**Trade Name:**

Neuro Assessment System, NAS-1000

**Generic/Common Name:**

Electronic Stethoscope

**Classification:**

21 CFR§870.1875

**Product Code:**

QBE

### PREDICATE DEVICE(S) [807.92(a)(3)]

The predicate device to support substantial equivalence of the NAS-1000 System is the 3M™ Littmann® Electronic Stethoscope, Model 3200 cleared under K083903.

### DEVICE DESCRIPTION [807.92(a)(4)]

The NAS-1000 System is a non-invasive, non-energy emitting device indicated for monitoring and recording of acoustic signals from the brain. The earbud passively receives the acoustic signal from the brain and the result is graphically displayed as an acoustic waveform on the monitor (NAS-1000M).

The NAS-1000 System consists of two components: a non-sterile, disposable, single patient use Headset (NAS-1000H) with four different sized earbuds (XS, S, M, L), and a tablet-based Monitor (NAS-1000M) which contains the software (NAS-1000S).

### INDICATIONS FOR USE [807.92(a)(5)]

The NAS-1000 System is a medical acoustic system intended as an adjunct to standard clinical practice for use in non-invasively monitoring, detecting, recording and displaying acoustic signals in the brain. It is used for any subject undergoing a physical examination and intended only for medical assessment purposes in a clinic or hospital.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]**

**Comparison of NAS-1000 System to Predicate Device**

| **Feature** | **HeadSense Neuro Assessment System, NAS-1000 (K172892)** | **3M™ Littmann® Electronic Stethoscope, Model 3200, K083903 (Primary predicate device)** | **Analysis of Differences** |
|---|---|---|---|
| Regulation/Classification | 21 CFR §870.1875 | 21 CFR §870.1875 | No difference. |
| Regulation Name | Stethoscope, Electronic | Stethoscope, Electronic | No difference. |
| Classification | II | II | No difference. |
| Product Code | DQD | DQD | No difference. |
| Indications for use | The NAS-1000 System is a medical acoustic system intended as an adjunct to standard clinical practice for use in non-invasively monitoring, detecting, recording and displaying acoustic signals in the brain. It is used for any subject undergoing a physical examination and intended only for medical assessment purpose in a clinic or hospital. | 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment. | Proposed intended use is the same as K083903.<br><br>The subject device and the predicate device are intended for monitoring, detecting and recording acoustic signals / sounds electronically. |
| Anatomical Location | Brain | Heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. | Similar to K083903. The predicate device may be used for other internal organs (i.e., brain). The subject device is to be used for the brain only. |
| Environment of use | Clinic, treatment center or hospital. | Clinic or hospital. | No difference. |

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| Device Description | The NAS-1000 System is a non-invasive, non-energy emitting device indicated for monitoring and recording of acoustic signals from the brain. The earbud passively receives acoustic signals from the brain and the result is graphically displayed as an acoustic waveform on the monitor (NAS 1000M).<br><br>The NAS-1000 System consists of two components: a non-sterile, disposable, single patient use Headset (NAS-1000H) with four different sized earbuds (XS, S, M, L), and a tablet-based Monitor (NAS-1000M) which contains the software (NAS-1000S). | The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.<br><br>The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.<br><br>The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. The Model 3200 does not incorporate any off-the-shelf (OTS) software. The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery. | Similar to K083903. Both systems passively obtain acoustic signals / sounds generated by the patient's organ using a microphone.<br><br>Both systems process the acoustic signals / sounds and present them to the user.<br><br>The 3M Littmann Electronic Stethoscope presents the sounds in the form of audio signal to the user. The NAS-1000 System provides the acoustic signals / sounds in the form of a graphical (visual) output to the user. |
| Sterilization Method | Non-sterile | Non-sterile | No difference. |
| Biocompatible Blood, Body and Fluid Contacting Materials | Skin contact only | Skin contact only | No difference. |

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| **Power Source** | | | |
| Source Type | Battery | Battery | No difference. |
| Battery Type | Lithium ion<br>CR 2032 Lithium Ion<br>Coin Cell (Headset)<br>Lithium Ion, 4000 mAh<br>(Tablet) | One AA battery | The systems use different battery types sufficient for operation life for intended use. |
| Battery Operation Time | Up to 260 Hrs (Headset)<br>Up to 74 Hrs (tablet) | 50-60 Hours | The systems have similar operation times and have sufficient operation life for intended use. |
| **Functional** | | | |
| Binaural Headset | Yes | Yes | No Difference. |
| Chest-Piece | No | Yes | The NAS-1000 System utilizes an earbud design optimized for use in the head not the chest. |
| Sound Processing | Digital Signal Processor | Digital Signal Processor | No Difference. |
| Display Function | Yes | Yes | No Difference. |
| Display of Waveform | 3 views of total energy from spectrogram (vertical axes: 0-15 Hz, 0-25 Hz, and 0-45 Hz; horizontal axis: time (6 second intervals for all charts) | Can Toggle between phonogram and spectrogram (vertical axes: 0-500 Hz, horizontal axis: time). | Both display axes for frequency (Hz) and time (sec). The NAS-1000 System displays frequencies specific to acoustic signals /sounds generated in the brain while the 3M Littmann displays sounds for pulmonary, cardiovascular, or general use. |

| | | | |
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| Signal to Noise Ratio | 23 dBv | 20 dBv | The NAS-1000 System signal to noise ratio is 3 dBv higher than the 3M Littmann. Since the NAS-1000 System has a higher signal to noise ratio then the 3M Littmann, the NAS-1000 System would be expected to be at least as good as the 3M Littmann at distinguishing signal from noise. |
| Display Type | LCD | LCD | No Difference. |
| Select Filter | There is no selectable filter for the NAS-1000 System. | Bell (20-1000 Hz)<br>Diaphragm (20-2000 Hz)<br>Extend range (50-500 Hz) | The NAS-1000 System design records pre-specified frequencies (0-15 Hz, 0-25 Hz, 0-45 Hz) in the brain. The 3M Littmann filters are specific for frequency values for pulmonary, cardiovascular or general use. |
| Detect and Display Heart Rate Function | N/A | Yes | The NAS-1000 System displays acoustic signals / sound waveforms from the brain and does not detect or display heart rate function. |
| Detect and Display Heart Rate Range | N/A | 30-199 bpm | The NAS-1000 System displays acoustic signals / sounds from the brain and |

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| | | | does not detect or display heart rate function. |
| Record and Playback Function | N/A | Yes | Not a required feature. |
| Number of Record and Playback Sounds | N/A | Save up to twelve, 30-second sound tracks;<br>Latest 12 sound tracks for playback. | Not a required feature |
| Sound Amplifier | N/A | Yes, up to 24X | No sound is outputted |
| Volume Control | N/A | Yes | No sound is outputted |
| Volume Control Level | N/A | 1-9 level | No sound is outputted |
| Automatic Power Off | Yes | Yes | The tablet automatically powers off after 10 minutes. |
| Monitor Battery Life Function | Yes | Yes | Monitored on tablet user interface |
| Monitor Battery Life Degrees | 100 (percentage) | 4 degrees | The tablet displays battery life in increments of 1%, the Littman has an indicator for each ¼ of remaining life (for the 3M Littmann, each indicator is termed a "degree": 4 indicators represents full charge, 1 indicator represents ¼ charge, etc.,) |
| Sound Track Transfer Function | Yes | Yes | Wav files saved |
| Sound Track Transfer Interface | USB Cable | Bluetooth | Wav files may be transferred from the tablet via a USB cable |

### SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the NAS-1000 System is substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the NAS-1000 System is substantially equivalent to the predicate device.

### PERFORMANCE DATA [807.92(b)]

All necessary nonclinical testing was conducted on the NAS-1000 System to support a determination of substantial equivalence to the predicate device.

**[807.92(b)(1)] Nonclinical Testing Summary:**

The nonclinical bench testing included:

- Performance bench and functional testing
- Software testing
- Biocompatibility
- Electrical Safety and Electromagnetic Compatibility testing

Phantom Bench Testing was also performed to verify that the NAS-1000 System is able to monitor, detect, record and displaying an acoustic signal / sound. A Cranial Phantom Head test model was designed and used during this testing to compare the NAS-1000 System and the predicate device. A representative cyclic acoustic signal/sound was generated using a peristaltic pump in the phantom bench test model and the waveforms were recorded and compared for both the NAS-1000 System and the predicate to the known input signal from the phantom bench test model. The NAS-1000 System and the 3M Littmann e-Stethoscope performed comparably and were able to graphically display the simulated systolic pulse from the phantom. The "simulated systolic pulse" refers to the pulsations generated by the motor of the phantom bench test.

The collective results of the nonclinical testing demonstrate that the device meets its performance requirements and does not raise different questions of safety or effectiveness for measuring acoustic signals in the brain or presenting information to the clinician when compared to the predicate device.

**[807.92(b)(2)] Clinical Testing Summary:**

A performance testing study of the NAS-1000 System was conducted on volunteers to validate the measurement of acoustic data collected from recordings of brain acoustic signals / sounds. The study demonstrated the ability of the NAS-1000 System to detect and generate waveforms from the brain to provide a tool for monitoring brain acoustic signals / sounds over various time intervals.

A total of 50 volunteers were measured and monitored.

NAS-1000 System recording sessions were conducted for 20 minutes continuously with each volunteer, and raw data was passively recorded by the monitor software. The data was then analyzed retrospectively to display on the tablet in three frequency bands (0-15 Hz, 0-25 Hz, 0-45 Hz), and also converted and displayed the output into a 2D waveform. The tablet outputs demonstrate the ability of the NAS-1000 System to display brain acoustic signals / sounds of in the volunteers based on the analysis of waveform data.

**CONCLUSIONS [807.92(b)(3)]**

In summary, the NAS-1000 System and the 3M Littmann have the same intended use and similar technological characteristics. Differences in the technological characteristics have been evaluated and supported with appropriate testing. The collective performance testing including the phantom bench testing and clinical testing on volunteers demonstrate substantial equivalence to the predicate device. The NAS-1000 Systems meets its performance requirements and the differences in technological characteristics do not raise different questions of safety or effectiveness for displaying acoustic signals / sounds from the brain or presenting information to the clinician when compared to the predicate device.

**SUMMARY**

The NAS-1000 System is substantially equivalent to the predicate device.