March 8, 2024

Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
Bronwyn Kelly
Senior Regulatory Affairs Specialist
2568 Bristol Circle
Oakville, Ontario L6H 5S1
Canada

Re: K233649
Trade/Device Name: ALGO Pro Newborn Hearing Screener (ALGO Pro)
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: February 8, 2024
Received: February 8, 2024

Dear Bronwyn Kelly:

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K233649

Device Name
ALGO Pro Newborn Hearing Screener (ALGO Pro)

Indications for Use *(Describe)*
The ALGO Pro Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses Automated Auditory Brainstem Response (AABR®) technology for automated analysis of Auditory Brainstem Response (ABR) signals recorded from the patient. The screener is intended for babies between the ages of 34 weeks (gestation age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening. The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health and about to be discharged from the hospital. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

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.

510K Summary

Date: 12 February 2024

Submitted By: Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Contact Person: Bronwyn Kelly
Senior Regulatory Affairs Specialist
Natus Medical Incorporated
Tel: +353 (0)91 647400
Fax: +353 (0)91 630050
E-mail: Bronwyn.Kelly@natus.com

Proprietary Name: ALGO Pro Newborn Hearing Screener

Common Name: Stimulator, Auditory, Evoked Response

Regulation Number: 21 CFR 882.1900

Classification Name: Stimulator, Auditory, Evoked Response

Product code: GWJ

Device Class: II

Predicate Device: ALGO 5 510(k) number: K073665

DEVICE DESCRIPTION:

The ALGO® Pro is a fully automated hearing screening device used to screen infants for hearing loss. It provides consistent, objective pass/refer results. The ALGO Pro device utilizes Auditory Brainstem Response (ABR) as the hearing screening technology, which allows the screening of the entire hearing pathway from outer ear to the brainstem. The ABR signal is evoked by a series of acoustic broadband transient stimulus **(**clicks) presented to a subject's ears using acoustic transducers and recorded by sensors placed on the skin of the patient.

The ALGO Pro generates each click stimulus and presents to the patient's ear using acoustic transducers attached to disposable acoustic earphones. The click stimulus elicits a sequence of distinguishable electrophysiological signals produced as a result of signal transmission and neural responses within the auditory nerve and brainstem of the infant. Disposable sensors applied to the infant's skin pick up this evoked response, and the signal is transmitted to the screener via the patient electrode leads.

The device employs advanced signal processing technology such as amplification, digital filtering, artifact rejection, noise monitoring and noise-weighted averaging, to separate the ABR from background noise and from other brain activity.

The ALGO Pro uses a statistical algorithm based on binomial statistics to determine if there is a response to the stimulus that matches to the ABR template of a normal hearing newborn. If a response is detected that is consistent with the ABR template derived from normal hearing infants (automated auditory brainstem response technology, AABR), the device provides an automated 'Pass' result. A 'Refer' result is automatically generated if the device cannot detect an ABR response with sufficient statistical confidence or one that is consistent with the template.

The ALGO Pro system utilizes the following main components and accessories at minimum to achieve its intended use:

- Handheld screener
- Cable assemblies
    - Patient Cable Attachment (PCA)
    - Acoustic Transducer Assembly Cable (ATA)
- Single-use supplies
    - Disposable earphones (Flexi-coupler Earphones)
    - Disposable electrodes/sensors (Jelly Tab Sensors)

Other accessories available for use with the ALGO Pro include:

- AC/DC power supply and power cords
- DC/DC converter module
- Bassinet hook
- Docking station
- Mobile Cart, with room for accessories, supplies, storage and transport
- Wireless keyboard
- Wireless label printer
- Equipment Check Kit

INTENDED USE & INDICATIONS FOR USE:

The ALGO Pro Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses Automated Auditory Brainstem Response (AABR®) technology for automated analysis of Auditory Brainstem Response (ABR) signals recorded from the patient. The screener is intended for babies between the ages of 34 weeks (gestation age) and 6 months. Babies should be well enough to be ready for discharge from the hospital and should be asleep or in a quiet state at the time of screening. The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health and about to be discharged from the hospital. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

COMPARISON OF TECHNOLOGICAL CHARACTERISITICS WITH THE PREDICATE DEVICE

The subject and predicate device both operate on the technological principle of measuring the electrical activity in the auditory nerve and brainstem in response to sound stimuli. At a high level, the subject and predicate devices are based on the following same technological elements:

- Acoustic stimulus energy delivered (35 or 40 dB nHL)
- AABR screening algorithm
- Electrode cable ("PCA cable")
- Transducer cable ("ATA cable")
- Consumable supplies (Flexicoupler earphones and Jelly tab sensor electrodes)
- Screening workflow

- Equipment check kit

The following technological differences exist between the subject and predicate devices:

- Consolidated hardware architecture embodied in a portable handheld
- EEG preamplifier integrated into the handheld device
- Use of a docking station for the handheld device
- Use of a bassinet hook to secure the handheld device during screening
- Use of a smaller user interface display for portability
- Use of a rechargeable battery as a source of power for the handheld device
- Use of a different mobile cart. The predicate device can only be used as cart-based system whereas the subject device can be used as a cart based or handheld.
- Use of a different label printer and keyboard with wireless capabilities.
- Connectivity options limited to Bluetooth, USB, and Wi-Fi

Specification/ Feature	**ALGO Pro (subject)**	**ALGO 5 (predicate, cleared under K073665)**	**Comparisons (Similarities or Differences)**
General			
Intended Use & Indications for Use	The ALGO Pro Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses Automated Auditory Brainstem Response (AABR®) technology for automated analysis of Auditory Brainstem Response (ABR) signals recorded from the patient. The screener is intended for babies between the ages of 34 weeks (gestation age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening. The screener is simple to operate. It does not require special technical	The ALGO 5 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® (Automated Auditory Brainstem Response) technology. The screener is intended for babies between the ages of 34 weeks (gestational age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening. The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic	Same

Specification/ Feature	ALGO Pro (subject)	ALGO 5 (predicate, cleared under K073665)	Comparisons (Similarities or Differences)
	skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health and about to be discharged from the hospital. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.	training with the equipment is sufficient to learn how to screen infants who are in good health. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.	
Patient population	Newborns between the ages of 34 weeks (gestation age) and 6 months, well enough to be ready for discharge from the hospital.	Newborns between the ages of 34 weeks (gestation age) and 6 months, well enough to be ready for discharge from the hospital.	Same
Anatomical sites	External ear for acoustic stimulation; forehead, nape, and shoulder for electrode placement	External ear for acoustic stimulation; forehead, nape and shoulder for electrode placement	Same
Intended Users	ALGO Pro is intended to be used by audiologists, ear-nose-throat doctors, nurses and other health care professionals that are trained to provide hearing screening services. It is not intended to be operated by lay users.	ALGO 5 is intended to be used by audiologists, ear-nose-throat doctors, nurses and other health care professionals that are trained to provide hearing screening services. It is not intended to be operated by lay users.	Same
Where used	Well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, audiology suite, outpatient clinic, or doctor's office.	Well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, audiology suite, outpatient clinic, or doctor's office.	Same
Energy delivered	Acoustic	Acoustic	Same
Technological Characteristics			

ALGO Pro 510k

Specification/ Feature	ALGO Pro (subject)	ALGO 5 (predicate, cleared under K073665)	Comparisons (Similarities or Differences)
Hardware architecture	Handheld, battery operated device	Panel PC based with proprietary DSP based hardware used to execute AABR screening algorithm.	Similar – see substantial equivalence discussion
User interface	7-in Color LCD, with touchscreen;	17-in Color LCD with touchscreen;	Similar – see substantial equivalence discussion
Connectivity, Data Transfer	Bluetooth, USB, Wi-Fi	Ethernet, Wi-Fi, USB, CD-ROM	Similar – See substantial equivalence discussion
Power	Rechargeable Battery	AC Mains only	Similar – See substantial equivalence discussion
AABR Screening Technological Characteristics			
ABR Screening Technology	Proprietary ALGO AABR Screening Technology	Proprietary ALGO AABR Screening Technology	Same
ABR Detection Algorithm	Proprietary binomial statistical algorithm with template derived from normal hearing infants	Proprietary binomial statistical algorithm with template derived from normal hearing infants	Same
Consumables – Earphones and Electrodes	Proprietary Flexicoupler earphones and Jelly tab sensor electrodes	Proprietary Flexicoupler earphones and Jelly tab sensor electrodes	Same
Transducer	ATA cable (with integrated microphone and speaker)	ATA cable (with integrated microphone and speaker)	Same
Electrode Cable	PCA cable (with 3 electrode leads)	PCA cable (with 3 electrode leads)	Same
AABR Screening Workflow	Operation via touchscreen leveraging guided workflows for ease of use	Operation via touchscreen leveraging guided workflows for ease of use	Same

ALGO Pro 510k

Specification/ Feature	ALGO Pro (subject)	ALGO 5 (predicate, cleared under K073665)	Comparisons (Similarities or Differences)
Screening Modes	Sequential, Simultaneous, Left, Right Ear	Sequential, Simultaneous, Left, Right Ear	Same
Stimulus Signal	Click	Click	Same
Stimulus Intensity	35 dB nHL, 40 dB nHL	35 dB nHL, 40 dB nHL	Same
Stimulus Rate	Alternating 34/sec and 37/sec	Alternating 34/sec and 37/sec	Same
Result Interpretation	Device reports Pass or Refer test result requiring no interpretation	Device reports Pass or Refer test result requiring no interpretation	Same
Result representation	PASS/REFER	PASS/REFER	Same
Standards met			
Applied Standards	All relevant Electrical Safety and Biocompatibility standards	All relevant Electrical Safety and Biocompatibility standards	Same (see below for a detailed list of applied standards)

SUBSTANTIAL EQUIVALANCE DISCUSSION

The ALGO Pro device consolidates much of the hardware functionality in the predicate device into a battery-operated handheld form factor with a smaller 7-in LCD and capacitive touchscreen. Additionally, the ALGO Pro handheld integrates the functionality of the external EEG preamplifier cable found in the predicate device (see discussion below regarding the AABR measuring algorithm). The ALGO Pro hardware architecture employs multiple processor cores to provide the necessary computing power to execute the software user interface and the AABR screening algorithm. The ALGO Pro design enables it to be used with or without the cart accessory to provide additional portability, allowing users to conduct AABR screening tests in limited-space environments.

The ALGO Pro AABR algorithm and acoustic stimulus are identical to the predicate ALGO 5. Bench testing was performed for relevant audiological characteristics of the stimulus delivered to the patient as well as interpretation of the recorded potential (i.e., creating a PASS/ REFER/ INCOMPLETE result). The bench tests included frequency, timing, polarity and sound level of the stimulus, myogenic noise detection, ambient noise detection, electrode impedance and signal to noise measurements detectable by the device. Bench testing demonstrated substantially equivalent performance between the subject (ALGO Pro) and predicate device (ALGO 5).

ALGO Pro 510k

Like the predicate device, the ALGO Pro device is powered and operated by AC Mains power when placed in the accompanying docking station. In addition, the ALGO Pro handheld device can operate on the internal Li-Ion rechargeable battery. The ALGO Pro battery was independently tested to and complies with the applicable Li-Ion battery safety standard IEC 62133-2.

The ALGO Pro device uses similar connectivity options as the predicate device which include Bluetooth, USB, and Wi-Fi. The subject device does not support archiving patient data to a CD or connecting the device to a network with an ethernet cable as the predicate device. Instead, patient data is transferred to a PC through the USB port or wirelessly when connected securely to a remote drive location. All connectivity options were tested through formal verification testing.

The ALGO Pro mobile cart is a commercially available healthcare mobile cart with some minor customization to accommodate the ALGO Pro docking station and accessories. The mobile cart includes several ergonomic improvements not available in the predicate such as an adjustable work surface height (i.e., lift mechanism) which facilitates use of the cart while sitting or standing. The ALGO Pro cart is also much lighter, making it easier to maneuver and transport.

Screening tests are performed with the ALGO Pro handheld device placed on the cart, securely attached to the mobile cart's accompanying docking station. In addition, the ALGO Pro handheld gives the user the option to perform screening tests in space constrained locations that are difficult to access with the mobile cart. The bassinet hook on the ALGO Pro handheld allows the user to safely attach the device to a bassinet during the screening test. A wireless off-the-shelf keyboard and wireless label printer have been included to provide flexibility in placement on the cart. The ALGO Pro user interface and workflow is identical to the predicate device.

The ALGO Pro handheld, mobile cart, user interface and accessories were evaluated through formative and summative human factors\usability testing, which included simulated use of the ALGO Pro device with and without the use of the cart (i.e., handheld device only). Human factors\usability testing did not raise any concerns regarding safety and effectiveness.

The ALGO Pro system, which includes the cart and all other system accessories was also independently tested to applicable biocompatibility, Safety, EMC, Usability, and Software lifecycle standards and demonstrate the subject device is as safe and effective as the predicate device. Reliability testing was also conducted on the ALGO Pro device and accessories by a third party.

In conclusion, ALGO Pro is substantially equivalent to the predicate device ALGO 5 with respect to Intended Use, technological characteristics, and non-clinical Performance data.

PERFORMANCE DATA

ALGO Pro 510k

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation was conducted according to ISO 10993-1:2018. The following tests

were considered applicable:

- Cytotoxicity
- Sensitization
- Irritation

The device and its accessories are classified as limited contact (≤24 hours) contact and contact with Intact skin. No issues were found during biocompatibility testing.

Electrical safety, EMC, and other applied standards

The ALGO Pro system was tested to and complies with the following applicable safety, electromagnetic compatibility standards and all other applicable standards:

- IEC 60601-1 Ed. 3.2 en:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-40 Ed. 2.0 b:2016 Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC 60601-1-6: Ed. 3.2 b:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability,
- IEC 62366-1:2015+ AMD1:2020 (Ed.1.1) Medical devices - Application of usability engineering to medical devices.
- IEC62304 Medical Device Software – Software Lifecycle processes
- IEC 62133-2:2017 Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
- IEC 60601-1-2 Ed. 4.1 en:2020 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-4-2 Ed. 1.0 b:2016 Medical Electrical Equipment – Part 4-2: Guidance and Interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- FCC Part 15 Regulation for Radio Transmitters

Software Verification and Validation Testing

ALGO Pro 510k

Software Verification and Validation testing were conducted, and Basic Documentation Level was provided as recommended by FDA's Guidance for Industry and Staff 'Content of Premarket Submissions for Device Software Functions'.

Mechanical testing

- Drop and tumble testing (device, bassinet hook and patient cables)
- Patient cable bend cycle testing (PCA, ATA)
- PCA electrode cable clip cycle testing
- Power button cycle testing
- Connector mating cycle testing
- Bassinet hook cycle testing
- Docking station latch cycle testing
- Docking station pogo pin contact cycle testing

Clinical Performance of AABR Algorithm:

The algorithmic sensitivity of the ALGO AABR algorithm is 99.9% for each ear using binomial statistics. Independent clinical studies published peer-reviewed clinical performance data showed a combined overall sensitivity of 98.4%. Specificity of the ALGO device ranged from 96% to 98% in these studies. Relevant studies are listed in the section Clinical Performance Studies (see below) Equivalence of the ALGO Pro to the predicate device in sensitivity and specificity PASS/REFER results has been proven in bench testing.

The AABR algorithm used in the predicate ALGO 5 device was originally developed internally by Natus Medical, Incorporated. Therefore, proper implementation of the AABR algorithm in the subject device is well understood. The ALGO Pro device utilizes the exact same methods and parameters to evoke, record, process and detect ABR responses as implemented in the predicate ALGO 5 device.

The ABR template used in the ALGO Pro is based on the morphology of normal hearing, near threshold, infant ABR waveforms, determined by superimposing the responses of 35 neonates to 35 dB nHL click stimuli. The data was collected at Massachusetts Eye and Ear Infirmary during the design and development of the original automated infant hearing screener using ABR. This technology was originally commercialized as ALGO I device, and details of the ALGO technology, including the template and its collection info was provided under 510(k) submission K852687. The same template and detection algorithm has been used in all the subsequent FDA cleared ALGO devices, including ALGO 2 (K936039), ALGO 3 (K013137), ALGO 3i (K030823), and the predicate ALGO 5 (K073665).

The ABR template and AABR algorithm used in all ALGO devices were originally developed and validated in the following studies:

Clinical Performance Studies

- Peters, J. G. "An automated infant screener using advanced evoked response technology." The Hearing Journal 39 (1986): 25-30.
- Herrmann, Barbara S., Aaron R. Thornton, and Janet M. Joseph. "Automated infant hearing screening using the ABR: development and validation." American Journal of Audiology 4.2 (1995): 6-14.

Nonclinical performance data, including bench testing and code reviews during the verification phase, confirmed the equivalence of the acoustic stimuli, recording of evoked potentials, and proper implementation of the ABR template and algorithm. Furthermore, thorough testing of the AABR screening algorithm with both the subject and predicate devices support that device effectiveness supports substantial equivalence, eliminating the need for additional clinical performance data.

CONCLUSION

Device safety is demonstrated via non-clinical performance testing to support substantial equivalence. The hardware and software verification and validation activities demonstrate that the ALGO Pro performs as intended in the specified use conditions. During the verification phase, bench testing and code reviews demonstrated substantial equivalence of the ALGO Pro AABR screening algorithm to the predicate. The results of these activities demonstrate that the ALGO Pro is as safe, effective, and substantially equivalent to the predicate device.