October 14, 2021

Path Medical GmbH
Ing. Oswald
Managing Director
Landsberger Strasse 65
Germering, Bavaria 82110
Germany

Re: K211147
Trade/Device Name: ALGO 7i
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: September 9, 2021
Received: September 13, 2021

Dear Ing. Oswald:

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 Data base 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211147

Device Name
ALGO 7i

Indications for Use *(Describe)*
The ALGO® 7i Newborn Hearing Screener is a hand-held, portable hearing screener intended to objectively determine the hearing status of a newborn/infant from 34 weeks gestational age to 6 months old. Babies should be well enough for hospital discharge and should be asleep or in a quiet state at the time of screening.

Exclusion Criteria
The following criteria should be used to exclude an infant from screening with the Natus ALGO hearing screeners:
- Infants not between 34 weeks gestational and 6 months of age
- Infants on ventilators or in incubators
- Infants on CNS (central nervous system) stimulants
- Infants receiving ototoxic medications
- Infants with compromised skin or jaundice

ALGO 7i devices are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. Basic training with the device is sufficient for performing screening of patients in good health. It is not intended to be operated by lay users.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

SUBMISSION INFORMATION

Date of preparation:	October 14, 2021
510(k) Submitter:	PATH MEDICAL GmbH Landsberger Str. 65 82110 Germering Germany Phone: ++49-89-80076502 Fax: ++49-89-80076503
Contact Person:	Dr. Johann Oswald, Director Landsberger Str. 65 82110 Germering Germany Phone: ++49-89-80076502 Fax: ++49-89-80076503 Email: oswald@pathme.de

DEVICE INFORMATION

Device Name:	ALGO 7i
Device Trade Names:	ALGO 7i, A7i
Device Identification Codes:	101049
Common Name:	Evoked Response Auditory Stimulator
Classification Name:	Evoked Response Auditory Stimulator FDA 21 CFR section 882.1900

PREDICATE DEVICE

ALGO 3i	510(k) Number: K030823

REFERENCE DEVICE

SENTIERO	510(k) Number: K133012

DEVICE DESCRIPTION

ALGO 7i is an audiometric examination platform which consists of the ALGO 7i device with a touch screen display together with different accessories such as Multidata Cable, Docking Station, Patient Cable, ATA Cable. All connectors and transducers have a special mechanically coded plug-in order to ensure the correct connection to the device. All plugs of the transducers have a memory chip inside which stores the information about the respective transducer (including type of connector, calibration table). As a result, the ALGO 7i instrument can be connected flexibly to different ATA Cables while enabling the instrument to 'know' the calibration values and status of the connected Cable. This information is to guide the user (feedback via display) and help to ensure correct performance of the device. The ALGO 7i is designed as standalone examination platform and can be connected to a personal computer (PC) via USB using the Multidata Cable or the Docking Station for data review and management. The Device is portable and is meant to be mainly used as mobile device. Materials in contact with humans are selected to be biocompatible.

Additional features are direct printing of patient and measurement data on a label using label printer that can be connected via Multidata Cable or Docking Station.

The ALGO 7i offers hearing screening using AABR technology.

The measurement application is controlled from a self-contained firmware. The measurement flow is menu guided on a touch screen. Evaluation of test results is based on signal statistics. Besides that, result information is displayed as PASS/REFER/INCOMPLETE.

The ALGO 7i is designed to be used by trained personnel in a medical or home environment to examine hearing in infants from 34 weeks (gestational age) that are ready for discharge from the hospital up to 6 months old.

The following accessories are available to conduct a measurement:

- ATA (Acoustic Transducer Assembly) Cable: PATH ATA-S, ATA-L
    - Equivalent to Natus ATA Cables, equivalent to the cables used with the predicate ALGO 3i, similar to the PATH Ear Coupler Cables used with the reference Sentiero
- Electrode cable: PATH ABR-S, ABR-L
    - shielded, passive cable to connect the instrument to electrodes

These accessories can be connected to ALGO 7i using special color and mechanical coded plugs, which holds the information about the connected transducer / cable. By that, the firmware can

make use of this information and adapt the measurement procedure according to calibration values or provide information to the user via its display.

INDICATIONS FOR USE

The ALGO® 7i Newborn Hearing Screener is a hand-held, portable hearing screener intended to objectively determine the hearing status of a newborn/infant from 34 weeks gestational age to 6 months old. Babies should be well enough for hospital discharge and should be asleep or in a quiet state at the time of screening.

Exclusion Criteria

The following criteria should be used to exclude an infant from screening with the Natus ALGO hearing screeners:

- Infants not between 34 weeks gestational and 6 months of age
- Infants on ventilators or in incubators
- Infants on CNS (central nervous system) stimulants
- Infants receiving ototoxic medications
- Infants with compromised skin or jaundice

ALGO 7i devices are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses, and audiologically trained personnel. Basic training with the device is sufficient for performing screening of patients in good health. It is not intended to be operated by lay users.

INTENDED USE

ALGO 7i devices are designed for use in clinical environments, such as the well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, audiology suite, outpatient clinic, or doctor's office as well as in community settings. The ALGO 7i is not intended for use in oxygen-rich environments.

COMPARISON TO SIMILAR DEVICES

The ALGO 7i will be compared to the predicate device ALGO 3i in terms of intended purpose, physiological features, accessories and applied screening algorithm. For workflow, technology, applied standards and user interface a comparison will be drawn to the reference device Sentiero.
COMPARISON TO THE PREDICATE DEVICE ALGO 3i:

	ALGO 7i (subject)	**ALGO 3i (predicate)**	**Equivalency**
Intended purpose			
Intended Use	ALGO 7i devices are designed for use in clinical environments, such as the well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, audiology suite, outpatient clinic, or doctor's office as well as in community settings. The ALGO 7i is not intended for use in oxygen-rich environments.	The ALGO 3i screener is simple to operate and does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants correctly. A typical screening can be completed in 15 minutes or less in any clinical environment (i.e. well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office).	Same (different wording, description of ALGO 7i is more specific)
Indications for Use	The ALGO® 7i Newborn Hearing Screener is a hand-held, portable hearing screener intended to objectively determine the hearing status of a newborn/infant from 34 weeks gestational age to 6 months old. Babies should be well enough for hospital discharge and should be asleep or	The ALGO 3i Newborn Hearing Screener is a portable, noninvasive device for screening the hearing of infants between the ages of 34 weeks corrected gestational age and six months. Screening can be performed by trained personnel in any	Same

	in a quiet state at the time of screening. Exclusion Criteria The following criteria should be used to exclude an infant from screening with the Natus ALGO hearing screeners: ▪ Infants not between 34 weeks gestational and 6 months of age ▪ Infants on ventilators or in incubators ▪ Infants on CNS (central nervous system) stimulants ▪ Infants receiving ototoxic medications ▪ Infants with compromised skin or jaundice ALGO 7i devices are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. Basic training with the device is sufficient for performing screening of patients in good health. It is not intended to be operated by lay users.	clinical environment (i.e. well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office)	
Physiological features			
Biosignal	Evoked potential	Evoked potential	Same
Electrode position	Head and neck	Head and neck	Same
Stimulation target	Cochlea	Cochlea	Same
Biosignal generator	Auditory pathway	Auditory pathway	Same

EEG recording channels, number of electrode contacts	1,3	1,3	Same
Accessories			
Transducer	ATA-Cable (different plug)	ATA-Cable	Same
Electrode Cable	Patient Cable (shielded, 3 clamps) (different plug)	Patient Cable, (shielded, 3 clamps)	Same
Electrodes	Natus Jelly Tabs	Natus Jelly Tabs	Same
Ear Coupler	Natus FlexiCoupler	Natus FlexiCoupler	Same
Implementation details			
Screening options	Each ear individually, simultaneously or sequentially	Each ear individually, simultaneously or sequentially	Same
Stimulus	Click	Click	Same
Stimulus repetition rate	34/37 Hz	34/37 Hz	Same
Stimulus level	35, 40 dB nHL	35, 40 dB nHL	Same
Noise cancellation (acoustic & myogenic)	Ambient noise microphone (acoustic); Dual channel sampling (myogenic)	Ambient noise microphone (acoustic); Dual channel sampling (myogenic)	Same
Applied algorithm	Natus AABR	Natus AABR	Same
Result interpretation	By the device	By the device	Same
Result representation	PASS/REFER/ INCOMPLETE	PASS/REFER/ INCOMPLETE	Same

Table 5. 1 Comparison to predicate device

The ALGO 7i will issue a PASS result when it collects sufficient data to establish with > 99% statistical confidence that an ABR signal is present and consistent with the template. This confidence level can be reached at a minimum of 1000 sweeps for 35dBnHL screening, and 2000 sweeps for 40dBnHL screening. The ALGO screener will continue to collect data up to 15,000 noise-weighted sweeps. If it has not established with > 99% statistical confidence that the ABR signal is present after 15,000 noise-weighted sweeps, it will issue a REFER result. Aborting a test will result in an INCOMPLETE result. The same procedure is implemented in the predicate ALGO 3i.

The ALGO 7i uses the same patented signal processing technology to separate the ABR from background noise and other brain activity as the predicate ALGO 3i. These responses are matched against a stored pattern called a "template", derived from the ABRs of normal-hearing infants. The ALGO 7i must detect the ABR with very high statistical confidence in order to issue a PASS result. This technology includes a patented dual-artifact rejection system to prevent non-ABR activity

from contributing toward a PASS result. This ensures a very high degree of accuracy of the PASS result issued by an ALGO 7i device. The template cannot be replaced or modified.

In conclusion, the ALGO 7i system is substantially equivalent to the predicate device ALGO 3i in terms of intended use, accessories used, operating principle and algorithm.

COMPARISON TO REFERENCE DEVICE:

Design and working principles of ALGO 7i are very similar to Sentiero. The similarity can be attributed to the fact that the same engineers at PATH MEDICAL, who designed the Sentiero products, also designed the ALGO 7i. In order to expedite development, hardware properties (e.g. PCB design, housing, connectors) as well as firmware features (workflow, User Interface, development environment, compiler) were mirrored from the Sentiero (use of Sentiero Backbone as starting point of development). The ALGO 7i test method ABR is a subset of the test methods available on the Sentiero, which in addition to ABR also offers various different test methods such as OAE or TYMP as well as diagnostic modules. Due to the variety of available modules and their differences in operation principle, the comparison of the ALGO 7i to the reference device will be drawn to the Sentiero and its ABR module:

	ALGO 7i (subject)	**SENTIERO (reference)**	**Equivalency**
Intended Purpose			
Patient population	Newborn/infant from 34 weeks gestational age to 6 months old	All ages	Same (Subset)
Indications for Use	Determination of the hearing status of a newborn/infant	Determination of the hearing status	Same (Subset)
Intended User	Audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. It is not intended to be operated by lay users.	Audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals and audiologically trained technicians in a medical environment. It is not intended to be operated by lay users.	Same
Medical principle	Determination of hearing status by evoking and recording potentials in the auditory pathway.	Determination of hearing status by evoking and recording potentials in the auditory pathway.	Same

Technical implementation			
Mode of operation	Handheld, standalone	Handheld, standalone	Same
User interface	Branded and reduced version of the Sentiero user interface	Sentiero user interface	Same (Subset)
Workflow	Operation via touch screen, device control via header/footer, online information	Operation via touch screen, device control via header/footer, online information	Same
Battery	Rechargeable	Rechargeable	Same
Connectors for accessories	Push-pull ODU-Plug	Push-pull ODU-Plug	Same
Display	3.5” TFT-LC backlight touch-sensitive display	3.5” TFT-LC backlight touch-sensitive display	Same
Power plug	Medical grade	Medical grade	Same
Data transfer	USB (via Multidata cable or docking station)	USB	Same
PC software	PC Software for data analysis and archiving. User management configurable. Can be used to load data from/ to the device.	PC Software for data analysis and archiving. User management configurable. Can be used to load data from/ to the device.	Same
Applied standards	All relevant Audiology, Electrical Safety and Biocompatibility standards	All relevant Audiology, Electrical Safety and Biocompatibility standards	Same (For a detailed list of applied standards see below)

Table 5. 2 Comparison to reference device

The primary mechanical difference between ALGO 7i and Sentiero is the charging of the built-in rechargeable batteries. ALGO 7i can be connected to a docking station or a dedicated multidata cable for charging and data transfer. In contrast thereto, Sentiero must be connected to a custom-made plug for connecting to the charger.

Due to the similarity in hardware and workflow, the ALGO 7i and Sentiero require compliance to the same standards. Both Devices show similar performance data and compliance to the following standards:

- **EN 10993-1:2018** Biological evaluation of medical devices (relevant tests: Cytotoxicity, Sensitization, Irritation)
- **ISO 15223-1:2012** Symbols, labeling, and information to be provided

- **IEC 60601-1:2005/AMD1:2012** Medical Electrical Equipment: General requirements for safety and essential performance
- **IEC 60601-1-2:2014** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- **IEC 60601-1-4:1996** Programmable electrical system
- **IEC 60601-1-6:2010** Usability
- **IEC 60601-2-40:1998** and **2016** Safety of electromyographs and devices for evoked potentials
- **IEC 62304:2010** Software lifecycle
- **EN 1041:2013** Information provided by the manufacturer
- **IEC 60645-7:2009** Acoustically evoked potentials
- **EN 60645-3:2007** Electroacoustics: Audiometric Equipment – Part 3: Test signals of short duration
- **EN 62366:2008 + A1:2015** Application of usability engineering to medical devices

In conclusion, ALGO 7i is substantially equivalent to the reference device Sentiero with respect to technological characteristics and non-clinical performance data.

Biocompatibility testing

The biocompatibility evaluation was conducted according to ISO 10993-1:2018. Following tests are considered applicable:

- Cytotoxicity
- Sensitization
- Irritation

The device and its accessories are classified as short-term contact and contact with skin. No issues were found during biocompatibility testing.

Electrical safety and electromagnetic compatibility (EMC)

The ALGO 7i was tested according to and complies to following electrical safety and electromagnetic compatibility standards: IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-2-40:1998 and 2016.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Mechanical and Acoustic Testing:

- Tensile strength of accessory cable
- Flex life of accessory cable
- Frequency content, polarity, timing, sound level, and repetition rate of the Click stimulus equivalent to the predicate ALGO 3i stimulus

- Similar myogenic and acoustic noise detection and rejection, impedance detection of the ALGO 7i to the predicate ALGO 3i
- Maximum possible sound level will remain below a possibly threatening level even under failure
- Push, Drop, and Mould Stress Relief test

Sensitivity and Specificity for PASS/REFER:

The algorithmic sensitivity of the ALGO is set to 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 Studies. Equivalence of the ALGO 7i to the predicate device in result detection has been proven in bench testing.

Clinical Performance Data:

No clinical performance data was collected for the subject device, ALGO 7i. The core automated ABR (AABR) technology is licensed from the predicate device ALGO 3i's manufacturer, Natus Medical Incorporated. ALGO 7i's substantial equivalence to predicate ALGO 3i was the main design goal. This was accomplished with the direct incorporation of this licensed technology, including the weighted-binary template-matching algorithm and associated ABR template used in ALGO 3i. Therefore, ALGO 7i device utilizes the exact same methods and parameters to evoke, record, process and detect ABR responses as implemented in the predicate ALGO 3i device. The equivalency of the presented stimulus and the use of the identical algorithm for interpretation of the recorded signal demonstrates substantial equivalence of the subject device to the predicate device in terms of clinical performance. As such, additional clinical performance data was not needed.

The equivalency of the acoustic stimuli and recording of the evoked potentials as well as the correct implementation of the template and algorithm was established with nonclinical performance data and code reviews during the verification phase. Additionally, the literature review in the clinical evaluation shows that the implementation of ABR screening on the ALGO 7i, which is identical to the implementation on the ALGO 3i, matches the current state of the art.

The ABR template used in the ALGO 7i is based on the morphology of normal hearing, near-threshold, infant ABR waveforms, determined by superimposing the responses of 35 neonates to 35 dBnHL 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), the predicate ALGO 3i (K030823), and ALGO 5 (K073665).

The template and AABR algorithm used in all ALGO devices were developed and validated in the following 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.

SUBSTANTIAL EQUIVALENCE

The ALGO 7i's stimulus input and measuring algorithm are identical to the predicate ALGO 3i. Bench testing was performed for relevant audiological characteristics of the stimulus delivered to the patient as well as interpretation of the recorded potential (creating a PASS/REFER/INCOMPLETE result). The bench tests included frequency, timing, polarity and sound level of the stimulus as well as noise resistance and the lowest potential measurable or detectable by the device. Additionally, biocompatibility, electrical safety, and EMC testing was conducted to demonstrate that the subject device is as safe and as effective as the predicate device. Although the hardware was updated with the state-of-the-art hardware (touch sensitive, colored display, PCB layout, robust Patient Cable, Smaller, color and mechanically coded plugs instead of D-SUB 9 plugs, more powerful, but smaller battery, lightweight material), bench testing demonstrated substantially equivalent performance between subject (ALGO 7i) and predicate device (ALGO 3i).

The ALGO 7i hardware is based on the reference device (Sentiero). The ALGO 7i uses the same material and manufacturer for the housing, sockets, plugs, charger, display and PCB as the Sentiero device. The well-known LiIon battery technology as incorporated in the Sentiero was used in the ALGO 7i. Additionally, the user interface and PCB design of the ALGO 7i is based on the Sentiero.

The biocompatibility and electrical safety as well as EMC of the hardware was independently verified by external laboratories.

Main differences between the subject ALGO 7i and the predicate ALGO 3i are the hardware changes as described above and their implication on the handling of the device. The screen displays information in color, facilitating e.g. differentiation of ears by color coding according to audiological conventions (right ear = red, left ear = blue). Also, the operating principle changed to maneuvering through the device by swiping and scrolling as current standard for e.g. smartphone use. This was enabled by implementing a touch- sensitive color display. The weight reduction makes the device easier to handle and carry, while color and mechanical coding minimizes the risk of using the wrong connector. Those features have been used in the reference device Sentiero for years without any adverse events reported.

Summarized, the main differences of the ALGO 7i compared to the predicate ALGO 3i represents a design which has been independently tested by third parties, bench tested and a long history of use for the same intended use. The differences between the subject ALGO 7i and predicate ALGO 3i do not raise any new questions concerning safety or effectiveness.
Nonclinical performance testing has shown that the ALGO 7i is substantially equivalent to the ALGO 3i.

It can be concluded, that the ALGO 7i is substantially equivalent to the ALGO 3i in terms of measuring performance based on stimulus and algorithm and substantially equivalent to the reference Sentiero in terms of hardware and user interface.

OVERALL CONCLUSION

The ALGO 7i shows similar safety, effectiveness and performance data as the predicate ALGO 3i. Through modernization of the hardware platform as well as the update of the applicable standards to their most recent versions and implementation of new relevant standards such as IEC 62366, the ALGO 7i is a state-of-the-art newborn hearing screener.