



April 14, 2025

Neuralynx, Inc.
Kelly Moeykens
Quality System Officer, QA/RA Manager
105 Commercial Drive
Bozeman, Montana 59715

Re: K250094

Trade/Device Name: Atlas Stim Headbox (NK) (31-0601-0077); Atlas Stim Headbox (Touchproof) (31-0601-0089); Atlas Stim Headbox (HD) (31-0601-0132); ASHB FIBER OPTIC DUPLEX CONN 2m (31-0204-0001); ASHB FIBER OPTIC DUPLEX CONN 7m (31-0204-0002); ATLAS Stim Headbox Software (36-0301-0006); Atlas Headbox Interface Cable (NK) (31-0204-003); Atlas Headbox Interface Cable (Touchproof) (31-0204-004); Atlas Headbox Interface Cable (HD) (31-0204-005); Atlas Headbox Expansion Panel (31-0607-0014)

Regulation Number: 21 CFR 882.1310

Regulation Name: Cortical Electrode

Regulatory Class: Class II

Product Code: GYC, GZL

Dated: January 13, 2025

Received: January 14, 2025

Dear Kelly Moeykens:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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,

 Patrick
Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K250094

Device Name

ATLAS Stim Headbox

Indications for Use (Describe)

The ATLAS Stim Headbox is a low power, constant current or voltage mode, bi-phasic stimulator intended for cortical or intracranial stimulation during electroencephalography examinations (i.e. stereoEEG).

The stimulation is applied to the brain using third-party stimulation probes (including cortical or intracranial electrodes) and the resulting cortical or deep brain potentials themselves are recorded using third-party cortical or intracranial electrodes.

The ATLAS Stim Headbox itself is an accessory to the ATLAS Neurophysiology System and ATLAS STIM Headbox software. The stimulation parameters, the electrodes selection and the activation of the stimulation current are all set-up and controlled from these devices. The ATLAS Stim Headbox can operate only when so connected and with the Pegasus and ATLAS Stim Headbox software; it cannot serve as a stand-alone stimulator.

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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K250094
Traditional 510(k) SUMMARY
ATLAS Stim Headbox

Date Prepared:	April 11, 2025
Submitter Information	
<i>Company and Manufacturer Name:</i>	Neuralynx, Inc.
<i>Contact Person:</i>	Name: Kelly Moeykens Phone: (207) 666-5651 Ext. 2195 Fax: (207) 666-8292
Device Information	
<i>Trade Name:</i>	Atlas Stim Headbox (NK), Atlas Stim Headbox (Touchproof), Atlas Stim Headbox (HD), ASHB FIBER OPTIC DUPLEX CONN 2m, ASHB FIBER OPTIC DUPLEX CONN 7m, ATLAS Stim Headbox Software, Atlas Headbox Interface Cable (NK), Atlas Headbox Interface Cable (Touchproof), Atlas Headbox Interface Cable (HD), Atlas Headbox Expansion Panel
<i>Common Name:</i>	ATLAS Stim Headbox, ASHB
<i>Classification and Product Code:</i>	21 CFR 882.1310 Class II GYC – electrode, Cortical GZL, Depth Electrode

<i>Device Class:</i>	Class II
Predicate Device:	K180761 SD LTM STIM Cortical Stimulator micromed S.p.A. 21 CFR 882.1310, GYC, Class II, Cortical electrode K183123 microTargeting Guideline 4000 5.0 System FHC, Inc. 21 CFR 882.1330, GZL, Class II, Depth Electrode

Device Description	The ATLAS Stim Headbox (ASHB) is a clinical headbox that allows 3rd party Macro electrode contact electrode arrays (ECoG, depth electrodes, grid array, strip array, etc.) to interface with the Neuralynx ATLAS Neurophysiology System, previously cleared in 510(k) K110967, which includes the Pegasus Software. The ATLAS Stim Headbox is an accessory to the ATLAS Neurophysiology System (formerly known as SpikeTrax in K110967). The ATLAS Stim Headbox hardware consists of an encased amplifier and embedded firmware for generation and delivery of stimulation energy. The ATLAS Stim Headbox can deliver electrical stimulation current under the control of the associated ATLAS Stim Headbox Software which interfaces via a fiber optic ethernet communications connection.
Intended Use:	The ATLAS Neurophysiology System and accessories are intended to be used in an EMU or similar clinical setting by Neurosurgeons, Physicians, and EEG Technicians within the neurology field for temporary monitoring, recording, and stimulation of neural activity within the brain. No age limit is imposed, as SEEG can be performed on very young patients or older adults. SEEG is reserved for selected and particularly complicated cases, and physician discretion is required when stimulation is indicated for cortical mapping based on multiple factors including age group.
Technological Comparison	Neuralynx, Inc. intends to commercially market the subject Atlas Stim Headbox and accessories for use in conjunction with the Atlas System (cleared via 510 (k) K110967). We submit that the Atlas Stim Headbox is substantially equivalent to the SD LTM STIM Cortical Stimulator cleared

via K180761 and secondarily to the Guideline 4000 5.0 System cleared via K183123.

The subject Atlas Stim Headbox has equivalent intended use and indications for use as the predicate device and employs the same fundamental scientific technology as the predicate device. In addition, the Atlas Stim Headbox and the predicate devices serve the same patient population, function on equivalent principles of operation, functional components & materials, exposure duration, treatment intervals, and basic design elements.

Although there are technological characteristic differences between the predicate (primary) SD LTM STIM Cortical Stimulator, (secondary predicate) Guideline 4000 5.0 System and Atlas Stim Headbox (subject device), these elements do not raise different questions of safety and effectiveness.

The technological characteristic differences are summarized below:

- An increased number of output stimulation channels (32) as compared to predicates (1 and 16, respectively for K180761 and K183123), which could potentially lead to an increase in the total amount of current delivered as compared to the predicates.
Analysis: There is no risk of increased cumulative current resulting from the higher number of channels offered by the ASHB Stim Headstage due to its enforcement of five safety rules that all uploaded stimulation protocols must pass prior to stimulation. The requirement that at any instantaneous moment in time the net sum of all currents flowing from all channels between the stimulator and the patient is required to be zero, eliminates any such concerns.
- Increased Maximum Stimulation pulse width duration, frequency, and pulse length compared to both predicates.

Analysis: Pulse Width: The pulse width is limited to less than or equal to 5mS by the ASHB. While this is 5 times larger than the maximum pulse width of the primary predicate, the ASHB also enforces a rule limiting the amount of charge per pulse phase to less than 20µC, this limitation works in conjunction with the pulse width to limit the amount of charge per pulse. In order to meet both requirements, a pulse of 5mS duration could only have an amplitude of 4mA or less ($5\text{ms} * 4\text{mA} = 20\mu\text{C}$). This compares more favorably with the primary predicate which would allow a 1mS pulse at 15mA (15µC max) and the secondary predicate which allows 3ms pulse duration with

10mA current (30 μ C max). Looking at the maximum pulse width alone does not accurately reflect that the ASHB provides a substantially equivalent limitation on the amount of charge per phase which can be specified and therefore provides an equivalent degree of safety.

Frequency: similar to pulse width, there is no user control for the direct setting of frequency. The upper limit listed of 5.0kHz is a result of the 25 μ S sampling rate of the stimulator. It is possible to define a pulse sequence of: (+1, +1, +1, 0, -1, -1, -1, 0) ... which would have an effective frequency of $1/(8 * 25\mu S) = 5.0\text{kHz}$. The device is designed to support many clinical applications requiring stimulating neuronal elements, including cell bodies (e.g. cerebral gray matter) and axons (fibers, peripheral nerves), regardless of their location in the central nervous system or peripheral system. Some clinical applications require longer pulse durations, like stimulating peripheral somatosensory neurons for evoking somatic sensations like itch, pain, temperature, and touch.

As a single example referring to the itch sensation, in Solinski HJ, Rukwied R. Electrically Evoked Itch in Human Subjects. Front Med (Lausanne). 2021 Jan 20;7:627617. doi:

10.3389/fmed.2020.627617, protocols using pulse durations as high as 7 ms and frequencies up to 2 kHz are mentioned.

Intracranial stimulation with frequencies as high as 500 Hz have been used by Usui N, Terada K, Baba K, Matsuda K, Tottori T, Umeoka S, Mihara T, Nakamura F, Usui K, Inoue Y.

Extraoperative functional mapping of motor areas in epileptic patients by high-frequency cortical stimulation. J Neurosurg. 2008 Oct;109(4):605-14. doi:

10.3171/JNS/2008/109/10/0605. A recent study Giovannelli G, Pelliccia V, Abarrategui B, Scarpa P, Revay M, Tassi L.

Intermediate stimulation frequencies for language mapping using Stereo-EEG. Clin Neurophysiol. 2022 Dec;144:91-97. doi:

10.1016/j.clinph.2022.10.003 described a clinical protocol for language mapping in humans using frequencies of 6, 9, and 12 Hz. train durations of 15 seconds. Another study, Hays MA, Smith RJ, Haridas B, Coogan C, Crone NE, Kang JY. Effects of stimulation intensity on intracranial cortico-cortical evoked potentials: A titration study. Clin Neurophysiol. 2021 Nov;132(11):2766-2777. doi: 10.1016/j.clinph.2021.08.008 used 50 pulses at a rate of 0.4 Hz, for a total duration of 125 seconds.

	None of these studies reported adverse effects of the stimulation protocols used. Addressing such diverse needs from clinical users of the system, to increase the customer base, has been behind the decision to increase the range of pulse durations and stimulation frequencies. Through the risk analysis and evaluation, it was determined that a visual indicator would be sufficient to mitigate risks of patient safety or effectiveness due to the use of device. The differences noted above do not introduce any new safety issues.
Basis for Equivalence	Descriptive characteristics between the subject and the predicate device present notable similarity. Nevertheless, to verify this position performance data is also available further demonstrating substantial equivalence.
Performance Testing	To account for the proposed changes in this 510(k) submission, non-clinical performance testing was submitted in the form of verification and validation and related risk management updates demonstrate that the performance parameters subject device are substantially equivalent to that of the predicate devices. Performance data of the ATLAS Stim Headbox is documented in the verification and validation reports. Electrical Safety Test, Mechanical Integrity test, Evoked Response, Electroencephalograph, and Software regression tests were performed on the system to determine substantial equivalence to the predicate system. Electrical Safety Testing: Electrical Safety consistent with IEC 60601 (Class 1 ME Equipment) Internal Testing based on IEC 60601 Protocols and 13485 product development processes 60601-1 electrical safety testing performed externally by 3rd party entity Mechanical Integrity: Mechanical strength and integrity testing consistent with standard IEC 60601. Internal Testing based on IEC 60601 Protocols and 13485 product development processes 60601-1 electrical safety testing performed externally by 3rd party entity Evoked Response: Evoked response testing is consistent with standard IEC 60601 and particular standard 60601-2-40 Internal testing based on 60601 protocols and 13485 product development processes 60601-2-40 evoked response testing performed externally 3rd party entity

	Electroencephalograph: Electroencephalograph testing is consistent with standard IEC 60601 particular standard 80601-2-26 Internal testing based on 60601 protocols and 13485 product development processes 80601-2-26 electroencephalograph testing performed externally 3rd party entity Software Regression Testing: The internally created software regression test protocol is based on the workflow established in the usability specification of the predicate device. It is performed iteratively at each software release per IEC 62304. All major and minor software functions were tested iteratively prior to each release of a new software revision. Additionally, bugs fixed since the previous round of regression testing were assessed for effectiveness and risk.
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Table: Comparison of Technological Characteristics

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
510(k) number	K250094	K180761	K183123	--
Device Name and Model	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	--
Manufacturer	Neuralynx, Inc.	MICROMED S.P.A.	FHC, Inc.	--
Classification Name	electrode, cortical electrode, depth	electrode, cortical	electrode, depth	Similar
Product Codes	GYC, GZL	GYC	GZL	Similar
Regulatory Class	II	II	II	Similar

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
Classification Number	882.1310 882.1330	882.1310	882.1330	Similar
Indications for Use (IFU) statement	The ATLAS Stim Headbox is a low power, constant current or voltage mode, bi-phasic stimulator intended for cortical or intracranial stimulation during electroencephalography examinations (i.e. stereoEEG). The stimulation is applied to the brain using third-party stimulation probes (including cortical or intracranial electrodes) and the resulting cortical or deep brain potentials themselves are recorded using third-party cortical or intracranial electrodes. The ATLAS Stim Headbox itself is an accessory to the ATLAS Neurophysiology System and ATLAS STIM Headbox software. The stimulation parameters, the electrodes selection and the activation of the stimulation current are all set-up and controlled from these devices. The ATLAS Stim Headbox can operate only when so connected and with the Pegasus and ATLAS Stim Headbox software; it cannot serve as a stand-alone stimulator.	The SD LTM STIM is a low power, constant current, bi-phasic stimulator intended for cortical stimulation during electroencephalography examinations (i.e. stereoEEG). The stimulation is applied to the brain using third-party stimulation probes (including cortical or intracranial electrodes) and the resulting cortical or deep brain potentials themselves are recorded using third-party cortical or intracranial electrodes. The SD LTM STIM itself is an accessory to the SD LTM 64 EXPRESS Signal Acquisition System and SystemPlus EVOLUTION software. The stimulation parameters, the electrodes selection and the activation of the stimulation current are all set-up and controlled from	The microTargeting™ Guideline 4000 5.0 System is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.	Similar indications to primary predicate.

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
		these devices. The SD LTM STIM can operate only when so connected and with the SystemPlus EVOLUTION software; it cannot serve as a stand-alone cortical stimulator.		
Intended User	Neurosurgeons, Physicians and EEG Technicians	Unknown	neurosurgeon, neurologist or clinical neurophysiologist	Similar
Electrical Safety Standards	IEC 60601-1:2005 ed.3+A1;C1:2014 Collateral standards IEC 60601-1-2:2014 Ed 4.1 IEC 60601-1-6:2010+AMD1:2013 IEC 62304:2006 Ed.1 + A1 IEC 62366:2007 Ed.1 +A1 Particular Standards IEC 80601-2-26:2019 Ed. 1.0 IEC 60601-2-40:2016 Ed. 2	60601-1:2005 +A1:2012 (ed.3.1), 60601-2-26:2012, third edition, 60601-1-2 (EN 60601-1-2 fourth ed. - 2014), 60601-2-40:2016, 62304:2006	Electrical Safety consistent with IEC 60601 (Class 1 ME Equipment) Internal Testing based on IEC 60601 protocols. 60601-1 Electrical Safety Testing Performed Externally by 3rd Party entity. Mechanical Strength and Integrity testing consistent with standard IEC 60601 Internal Testing based on IEC 60601 protocols. 60601-1 Mechanical Strength Testing Performed Externally by 3rd Party entity. The internally created software regression	Subject device conforms to updated versions of FDA-recognized standards.

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
			test protocol is based on the workflow established in the Usability specification of the predicate device. It is performed iteratively at each software release per IEC 62304.	
Interface to Computer	Stand-alone Software application provides user control of stimulation functionality and integrates with the Pegasus software of the ATLAS Neurophysiology System for data acquisition.	Control of stimulation functionality is integrated into the SD LTM 64 EXPRESS Signal Acquisition System and SystemPlus EVOLUTION software.	Control of stimulation functionality is integrated into the Guideline 5 system's hardware and software application	The subject device differs from both predicates in that a separate application is used to control the stimulation functionality rather than having this integrated into the larger software application for the entire electrophysiology system. This is not a clinically relevant distinction as it introduces no additional risk or usability burden over the predicates. The stand-alone software

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
				application of the subject device will not allow stimulation unless the Pegasus software of the Atlas Neurophysiology System is also running and communication between the two applications has been established.
Stimulus Output Channels	64 Channels	64 Channels	16 Channels	The Subject Device has the same number of available stimulation channels as the primary predicate
Impedance Check	Yes, 100 Ω to 5 M Ω	Unknown	Yes, 100 Ω to 5 M Ω	The Impedance Check ranges of the subject device are the same as those of the secondary predicate device. Regarding the primary predicate: publicly available information does not describe a method for using the

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
				stimulator to check impedance. However, it is expected that impedance is checked as part of the larger SD LTM 64 EXPRESS Signal Acquisition System.
Number of stimulus output Channels capable of simultaneous stimulus	32 Channels	2 Channels (one stimulus waveform applied between two contacts)	16 Channels	The Subject Device can stimulate on more channels simultaneously than either of the predicate devices. Like the secondary predicate, the subject device can support multiple stimulus waveforms across numerous contacts. Unique to the subject device, a software-based rule limits the total amount

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
				of current flowing through the patient at any instant across all active channels to less than 25mA.
Max Stimulation Charge (per channel, per phase)	20 μC per phase Max	15 μC per phase Max	30 μC Max, (parametric constant current)	Similar to the primary predicate
Stimulation Pulse Duration	25 μs to 5000 μs as defined by successive zero crossings of waveform	50 μs to 1000 μs in steps of 1 μs	Continuous 47 μs to 3000 μs	The subject device is most similar to the secondary predicate. The fact that longer pulse durations are allowed does not present any additional risk given that the subject device directly limits the charge per phase to 20 μC or less whereas the secondary predicate achieves its maximal charge per phase limit of 30 μC as a result of limiting the pulse width parameter to 3000 μs and the current to

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
				10mA. The differences in minimum pulse width are not clinically significant.
Electrical Modes	Constant Current, $\pm 12.5V$ compliance in two ranges: $\pm 10mA$ & $\pm 200\mu A$	Constant Current, $\pm 10V^1$ compliance in the range of $\pm 15mA$	Constant Current, $\pm 14V$ compliance in two ranges: $\pm 10mA$ and $\pm 100\mu A$	Similar to both predicates. The small variances in compliance voltage are not clinically significant. The subject device is similar to the secondary predicate in its use of distinct ranges with an upper limit of 10mA per channel.
Type of electrodes	510k cleared Cortical and depth Macroelectrodes, like the MICRODEEP Depth Electrode, D08-18AM	Cortical Macroelectrodes	Depth Microelectrodes & Depth Macroelectrodes	As discussed, there is no significant distinction between electrode contact size for cortical macroelectrodes (arrays/strips) vs. depth macroelectrodes (DBS, SEEG). Microelectrodes differ significantly though as the contact size is

Parameter	ATLAS Stim Headbox	SD LTM STIM Cortical Stimulator	Guideline 4000 5.0 System	Comment
				orders of magnitude smaller. Neither the subject device nor the primary predicate is suitable for microelectrode stimulation as the higher impedance of these electrodes tends to require a higher compliance voltage. The subject device labeling includes safety information related to use of the electrode.
Report Template	Current and Voltage monitoring can be visualized post stimulation via recorded voltage and current data.	Automated report provides visual documentation and audit of stimulations and responses	Visualization during procedure and data archived	Similar report features as predicates

Conclusion

The subject device is technologically similar to the predicate devices. The differences are limited to minor technological differences that do not impact substantial equivalence. The hardware and indications for use (IFU) statement are similar to the predicate and no changes have been made therein.

To account for the minor technological differences, nonclinical tests in the form of verification and validation have been provided to demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate devices.