December 31, 2025

Neurofield, Inc.
℅ Tom Renner
Quality, Efficiency & Regulatory Affairs Consultant
Vision 28
915 SW Rimrock Way
Suite 201 Pmb 402
Redmond, Oregon 97756

Re: K252951
Trade/Device Name: Genesis Sleep
Regulation Number: 21 CFR 882.5800
Regulation Name: Cranial electrotherapy stimulator
Regulatory Class: Class II
Product Code: QJQ
Dated: September 15, 2025
Received: September 16, 2025

Dear Tom Renner:

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) 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,

Heather L. Dean -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252951

Device Name
Genesis Sleep

Indications for Use *(Describe)*
Genesis Sleep is a non-invasive, clinical- and home-use neurostimulation device that is indicated to treat chronic insomnia in adults aged 22 and older.

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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Contact Details

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Device Name

Trade Name: Genesis Sleep
Common Name: Cranial electrotherapy stimulator
Classification Name: Cranial Electrotherapy Stimulator To Treat Insomnia And/Or Anxiety
Regulation Number: 882.5800
Product Code: QJQ

Legally Marketed Predicate Devices

510(k) Number: K230826
Device Name: Modius Sleep
Product Code: QJQ

Device Description Summary

Genesis Sleep is a non-invasive transdermal neurostimulation device to treat chronic insomnia. The device utilizes a technology known as electrical vestibular nerve stimulation (VeNS). It is indicated for clinical- and home-use to treat chronic insomnia in adults aged 22 and older.

It consists of a battery-powered device designed to transcutaneously deliver low-level electrical energy (up to 1 mA) to the skin behind the ears, over the mastoid processes. The

delivery of this neurostimulation is through two single-use self-adhesive electrode pads. These pads are placed on the skin behind each ear (mastoid area).

The intensity of the electric pulse can be adjusted up or down by the user. When turned on, the device delivers a small electrical impulse which stimulates the vestibular nerve. When the device is not being used, the battery can be charged using the charging station provided. Therefore, it is not physically possible to recharge the battery while the device is in use in stimulation mode.

The Genesis Sleep device exerts its therapeutic effect through electrical stimulation of the vestibular nerves. Electrical vestibular nerve stimulation (VeNS) is a non-invasive therapeutic method that applies pulsed, alternating microcurrent transcutaneously to the vestibular nerves via stimulation pads.

Genesis Sleep delivers this neurostimulation through two self-adhesive stimulation pads which are placed on the skin behind each ear (mastoid processes). When turned on, the device delivers a small electrical impulse which can be adjusted up or down by the user.

Substantial Equivalence Discussion

The comparison between the proposed Genesis Sleep device and the predicate Modius Sleep (K230826) below consists of a series of tables followed by explanations of the similarities and differences described in each table.

I. Summary of Substantial Equivalence

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
Indications for Use	Genesis Sleep is a non-invasive, clinical- and home-use neurostimulation device that is indicated to treat chronic insomnia in adults aged 22 and older.	Modius Sleep is a non- invasive, home-use neurostimulation device that is indicated to treat chronic insomnia in adults aged 22 and older.	The indications for use are materially the same. The proposed device indications include clinical use, whereas the predicate does not. Given that the labeling requirements for effective home use exceed those of clinical use, and considering that the

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
			device is prescription use only, this does not constitute a new intended use.
Environment	Clinical and Home	Home	*see Indications comment above.
Regulatory Class	Class II	Class II	Identical.
Classification Name	882.5800 - Cranial electrotherapy stimulator	882.5800 - Cranial electrotherapy stimulator	Identical.
Product Code	QJQ	QJQ	Identical.
Target Population	Adults 22 and older	Adults 22 and older	Identical.
Waveform	Symmetrical Biphasic Rectangular Wave	Symmetrical Biphasic Rectangular Wave	Identical.
Current Intensity Range	0 µA - 1000 µA	0 µA - 1000 µA	Identical.
Pulse Width Range	1 s	1 s	Identical.
Number of electrodes	2	2	Identical.
Electrode placement	Mastoid	Mastoid	Identical.
Power Source	12 V Li-Ion Battery	3.75 V Lithium Polymer Battery	
Frequency	0.25 Hz	0.25 Hz	Identical.
Treatment Range	30 min	30 min	Identical.
Unit Controls	PC-based Software	Built into the device	Different.
Dimensions	16.8 cm x 17.5 cm x 6.1 cm	16.5 cm x 15.1 cm x 6.6 cm	Similar.
Enclosure	Extruded Aluminum	Plastic	Different.

Discussion of Similarities and Differences

The two systems are identical in the following parameters:

- Regulatory Class
- Classification Name
- Product Code
- Target population
- Waveform

- Current intensity range
- Pulse width range
- Number of electrodes
- Electrode placement

The two systems differ in the following ways:

- The proposed Genesis Sleep indications include clinical use, whereas the predicate does not. Given that the labeling requirements for effective home use exceed those of clinical use, and considering that both devices are prescription use only, this does not constitute a new intended use.
- Both systems have been tested for safety and EMC. The proposed Genesis Sleep is also tested for use in the home healthcare environment.
- Although they have similar overall dimensions, the form factors of the two devices are different. The proposed Genesis Sleep is not intended to be worn.
- The enclosures are made of different materials.
- The controls of the proposed Genesis Sleep are not built into the device but are rather implemented via PC-based software.

These differences are minor, and do not materially affect their substantial equivalence with respect to technological basis or use.

II. Safety Parameters

Parameter	**Proposed Device Genesis Sleep**	**Predicate Modius Sleep (*K230826*)**	**Comment**
Electrical Safety	Complies with IEC 60601-1. Additionally, complies with IEC 60601-1-11.	Complies with IEC 60601-1.	The proposed device and predicate devices are identical with regards to 60601-1. The Genesis Sleep has additionally been tested to be used in the home environment.
EMC	Complies with IEC 60601-1-2.	Complies with IEC 60601-1-2.	Identical.
Software LOC/Documentation	Basic.	Moderate.	The proposed device and predicate devices are different.

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
Software V&V	Complies with FDA Guidance Requirement.	Complies with FDA Guidance Requirement.	Identical.
Biocompatibility	Complies with ISO 10993.	Complies with ISO 10993.	Identical.

Discussion of Similarities and Differences

The two systems are identical with respect to the following safety parameters:

- IEC 60601-1 compliance.
- IEC 60601-1-2 compliance.
- Software V&V compliance.
- Biocompatibility compliance.

The two systems differ in the following ways:

- The proposed Genesis Sleep has additionally been tested to the IEC 60601-1-11 standard.
- The Software LOC is different, reflecting evolving FDA guidance and terminology.

These differences are minor, and do not materially affect their substantial equivalence with respect to technological basis or use.

III. Technical Parameters

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
Power Source	12 V Li-Ion Battery	3.75 V Lithium Polymer Battery	Differs in supplied voltage, but both use lithium batteries.
Method of Line Current Isolation	DC:DC converter	DC:DC transformer	Same. Both use transformers for isolation.
Patient Leakage Current (as per ANSI/AAMI 60601-1)	0.8 µA	0 µA	Higher leakage current, but still within the allowable range.
Normal Condition (µA)	0-1000 µA	0-1000 µA	Identical.

Parameter	**Proposed Device Genesis Sleep**	**Predicate Modius Sleep (*K230826)***	**Comment**
Single Fault Condition (µA)	0.54 µA	2.3 µA	Better than predicate.
Average DC current through the electrodes when the device is on but no pulses are being delivered (µA)	0 µA	0 µA	Identical.
Number of output channels	1	1	Identical.
If more than one channel, is the stimulus delivered to each channel synchronous or alternating between each channel?	N/A	N/A	Identical.
If more than one channel, describe method of channel isolation	N/A	N/A	Identical.
Software/Firmware/ Microprocessor Control	Yes	Yes	Identical.
Automatic Overload Trip?	Yes	No	Better than predicate. Software continuously monitors current when delivering pulses
Automatic Shut Off?	Yes	Yes	Identical.
User Override Control?	Yes	Yes	Identical.
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Identical.
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Identical.

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
Maximum Output Voltage (volts) (+/- 1%)	500 mV @ 500 Ω 2 V @ 2 kΩ 10 V @ 10 kΩ	500 mV @ 500 Ω 2 V @ 2 kΩ 10 V @ 10 kΩ	Identical.
Maximum Output Current (specify units) (+/-2%)	1000 µA @ 500 Ω, 2 kΩ, and 10 kΩ	1000 µA @ 500 Ω, 2 kΩ, and 10 kΩ	Identical.
Duration of primary (depolarizing) phase (msec)	4000 (4 seconds)	4000 (4 seconds)	Identical.
Pulse Duration (msec)	2000 (2 second)	2000 (2 second)	Identical.
Frequency (Hz) [or Rate (pps)]	0.25 Hz	0.25 Hz	Identical.
For interferential modes only: Beat Frequency† (Hz)	N/A	N/A	Identical.
For multiphasic waveforms only: Symmetrical phases? Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	Identical.
Net Charge (microcoulombs (µC) per pulse) (If zero, state method of achieving zero net charge.)	1000 µC @ 2kΩ	1000 µC @ 2kΩ	Identical.
Maximum Phase Charge, (µC)	1000 µC @ 2kΩ	1000 µC @ 2kΩ	Identical.
Maximum Current Density (mA/cm^2, r.m.s.)	0.5 mA /cm^2 @ 500 Ω	0.5 mA /cm^2 @ 500 Ω	Identical.
Maximum Average Current (average absolute value), mA	1 mA @ 2 kΩ	1 mA @ 2 kΩ	Identical.

Parameter	Proposed Device Genesis Sleep	Predicate Modius Sleep (*K230826)*	Comment
Maximum Average Power Density, (W/cm^2), (using smallest electrode conductive surface area)	0.99 mW/cm^2 @ 2 kΩ	0.99 mW/cm^2 @ 2 kΩ	Identical.
Burst Mode (i.e., pulse trains) pulses per burst:	2	2	Identical.
Burst Mode bursts per second:	0.25	0.25	Identical.
Burst Mode burst duration (seconds):	4	4	Identical.
Burst Mode duty cycle:	0.5 (50%)	0.5 (50%)	Identical.
ON Time (seconds)	2 sec	2 sec	Identical.
OFF Time (seconds)	2 sec	2 sec	Identical.

Discussion of Similarities and Differences

The two systems are identical with respect to the following technical parameters:

- Method of Line Current Isolation
- Normal Condition current
- Single Fault Condition current
- Average DC current through the electrodes when the device is on but no pulses are being delivered
- Number of output channels
- Software/Firmware/Microprocessor Control
- Automatic Shut Off
- User Override Control
- Waveform (e.g., pulsed monophasic, biphasic)
- Shape (e.g., rectangular, spike, rectified sinusoidal)
- Maximum Output Voltage
- Maximum Output Current
- Duration of primary (depolarizing) phase
- Pulse Duration
- Frequency
- Net Charge
- Maximum Phase Charge

- Maximum Current Density
- Maximum Average Current
- Maximum Average Power Density
- Burst Mode (i.e., pulse trains) pulses per burst
- Burst Mode bursts per second
- Burst Mode burst duration (seconds)
- Burst Mode duty cycle
- ON Time (seconds)
- OFF Time (seconds)

The two systems differ in the following technical parameters:

- The proposed Genesis Sleep uses a different lithium battery voltage.
- The proposed Genesis Sleep has a higher leakage current, but still within the allowable range.
- The proposed Genesis Sleep is better in the single fault condition.
- The proposed Genesis Sleep has an Automatic Overload Trip, increasing safety.

These differences are minor, and do not materially affect their substantial equivalence with respect to technological basis or use.

IV. Output Parameters

Parameter	**Proposed Device Genesis Sleep**	**Predicate Modius Sleep (*K230826)***	**Comment**
Output value at 500 Ω, 2 kΩ and 10 kΩ load conditions	1 mA at all loads 0.25 Hz	1 mA at all loads 0.25 Hz	Identical.
Electrode surface area in cm^2	Conductive Area (16mm diameter) 2.0 cm^2	Conductive Area (16mm diameter) 2.0 cm^2	Identical.
Current density	0.5 mA/cm^2 @ 500 Ω, 2kΩ, and 10 kΩ	0.5 mA/cm^2 @ 500 Ω, 2kΩ, and 10 kΩ	Identical.
Charge density	497.63 µC/cm^2 per pulse@ 500 Ω, 2 kΩ, and 10 kΩ	497.63 µC/cm^2 per pulse@ 500 Ω, 2 kΩ, and 10 kΩ	Identical.
Power density	0.25 mW/cm^2 @ 500 Ω 0.99 mW/cm^2 @ 2 kΩ 4.97 mW/cm^2 @ 10 kΩ	0.25 mW/cm^2 @ 500 Ω 0.99 mW/cm^2 @ 2 kΩ 4.97 mW/cm^2 @ 10 kΩ	Identical.

Max phase charge (pulse width x peak current)	1000 µC per pulse @ 500 Ω, 2 kΩ, and 10 kΩ	1000 µC per pulse @ 500 Ω, 2 kΩ, and 10 kΩ	Identical.
Max phase charge density (pulse width x peak current) / electrode surface area	497.63 µC/cm^2 per pulse @ 500 Ω, 2 kΩ, and 10kΩ	497.63 µC/cm^2 per pulse @ 500 Ω, 2 kΩ, and 10kΩ	Identical.
Max average power density (Duty cycle x peak current)^2 x (load Ω) ÷ electrode surface area)	0.12 mW/cm^2 @ 500 Ω 0.5 mW/cm^2 @ 2 kΩ 2.49 mW/cm^2 @ 10 kΩ	0.12 mW/cm^2 @ 500 Ω 0.5 mW/cm^2 @ 2 kΩ 2.49 mW/cm^2 @ 10 kΩ	Identical.
Number of electrodes	2	2	Identical.

Discussion of Similarities and Differences

The two systems are identical with respect to all output parameters:

- Output value at 500 Ω, 2 kΩ and 10 kΩ load conditions
- Electrode surface area
- Current density
- Charge density
- Power density
- Max phase charge
- Max phase charge density
- Max average power density
- Number of electrodes

V. Comparative Performance Evaluations

Comparative performance evaluations were performed. The results demonstrate substantial equivalence of the proposed Genesis Sleep to the predicate device.

VI. Leveraged Clinical Data from Predicate Device (Modius Sleep, K230826)

To meet the special control requirement under 21 CFR 882.5800(b)(1)(vi)(E), the following provides a detailed summary of the clinical testing for the predicate device (Modius Sleep, K230826), including the clinical outcomes associated with its use and a summary of adverse events and complications that occurred with the device. This information is drawn from the predicate's 510(k) summary and the associated pivotal clinical study (published as Curry et al., Brain Stimulation 17 [2024] 782–793). A comparison of the predicate's stimulation parameters, treatment protocol, and device usage to those of the Genesis

Sleep is provided, followed by a justification for why the predicate's clinical data is pertinent and directly applicable to the Genesis Sleep.

Summary of Predicate Device Clinical Testing

The predicate device's clinical performance was evaluated in a pivotal randomized, double-blinded, sham-controlled trial to assess the safety and efficacy of the Modius Sleep for treating chronic insomnia. The study was multi-site, conducted from May 2022 to January 2023 at Ulster University (UK, including remote recruitment from the Republic of Ireland) and Hong Kong Polytechnic University (HK). It enrolled 149 participants aged 19-67 years with moderate to severe chronic insomnia (Insomnia Severity Index [ISI] score ≥15), confirmed via screening to align with ICSD and DSM-V criteria (e.g., sleep disturbance duration/frequency, daytime symptoms, adequate sleep opportunity, no co-existing conditions). Participants were randomized 1:1 to the Modius Sleep (n=75) or sham device (n=74). Both devices appeared identical, ensuring blinding.

Stimulation Parameters and Treatment Protocol Used in the Study:

- Waveform: Symmetrical biphasic rectangular.
- Frequency: 0.25 Hz.
- Current Intensity: 0.1 mA to 1.0 mA (user-adjustable in 0.1 mA increments until a gentle swaying sensation was felt, indicating vestibular nerve modulation).
- Pulse Duration: 2 seconds.
- Primary (Depolarizing) Phase Duration: 4 seconds.
- Burst Mode: 2 pulses per burst; 0.25 bursts per second; 4-second burst duration; 50% duty cycle.
- ON/OFF Time: 2 seconds each.
- Session Length: 30 minutes.
- Usage Frequency: Daily (28 consecutive days in UK; 5 days/week for 20 total days in HK).
- Placement: Bilateral on mastoid processes.
- Device Usage: At home, while sitting, immediately before sleep; self-adhesive electrode pads disposed after each use; intensity adjusted via device buttons; 16-hour post-session lockout to prevent overuse; device not rechargeable during stimulation for safety.

The sham device used a 0.8 Hz frequency (reducing vestibular stimulation likelihood), with stimulation ramping down to 0 mA after 30 seconds (total 50 seconds), exploiting user accommodation to current sensations for blinding.

Clinical Outcomes:

- Primary Outcome (ISI Score Change): In the complete case analysis (n=126), the Modius Sleep group had a mean ISI decrease of 5.80 (95% CI: -6.79 to -4.81;

p<0.001 within-group), vs. 3.52 (95% CI: -4.74 to -2.30; p<0.001) in sham. Between-group difference: -2.28 (95% CI: -3.85 to -0.71; p=0.005). Intention-to-treat (ITT) analyses (multiple imputation [MI] and last observation carried forward [LOCF]) showed similar trends, with Modius Sleep reductions of 5.78 (MI) and 4.95 (LOCF), approaching or meeting the 6-point clinically meaningful threshold for over half of the treatment group.

- Secondary Outcomes: Superior improvement in SF-36 energy/fatigue (ITT p=0.006; complete case p=0.004). Pittsburgh Sleep Quality Index (PSQI) global score improvements were greater in Modius Sleep but not statistically significant after corrections.
- Over 4 weeks, ISI scores decreased most from Week 0 to Week 2, then stabilized; scores remained low at Week 8 and 16 (exploratory follow-up in HK).

Adverse Events and Complications:

Twenty-two non-anticipated adverse events (AEs) were reported during the 4-week intervention (16 in Modius Sleep group, 6 in sham), all minor, self-resolving, and causing minimal discomfort. No serious device-related AEs or complications occurred. One non-device-related serious AE (minor cerebrovascular accident due to undiagnosed hypertension) was reported post-withdrawal. AE breakdown:

Body System / Reported Term	Total n (%)	Modius Sleep n (%)	Sham Control n (%)
Nervous System Disorders - Headache/migraine	7 (4.7)	6 (4.0)	1 (0.7)
Eye Disorders - Flashes in peripheral vision	2 (1.3)	2 (1.3)	0 (0)
Eye Disorders - Shadow in peripheral vision	1 (0.7)	1 (0.7)	0 (0)
Eye Disorders - Tingling in eye	1 (0.7)	1 (0.7)	0 (0)
Ear Disorders - Ear pain	2 (1.3)	0 (0)	2 (1.3)
Ear Disorders - Tinnitus	2 (1.3)	1 (0.7)	1 (0.7)
Ear Disorders - Itching in ear	1 (0.7)	0 (0)	1 (0.7)
Mood Disorders - Low Mood	2 (1.3)	2 (1.3)	0 (0)
Mouth/Dental Disorders - Metal fillings pulsing	1 (0.7)	0 (0)	1 (0.7)
Mouth/Dental Disorders - Grinding teeth	1 (0.7)	1 (0.7)	0 (0)

Body System / Reported Term	Total n (%)	Modius Sleep n (%)	Sham Control n (%)
Gastrointestinal Disorders - Nausea	1 (0.7)	1 (0.7)	0 (0)
Other - Tingling in arm	1 (0.7)	1 (0.7)	0 (0)

Rates were similar to sham, indicating low device-specific risk. No withdrawals due to AEs except one (treatment group: nausea and headaches). Generalizability: Baseline ISI scores (HK 19.11, UK 18.82) comparable to US studies (e.g., 17-17.8); insomnia prevalence in HK (20.7%) aligns with US/global estimates (10-20%); no evidence of racial/ethnic differences in insomnia presentation.

Comparison of Stimulation Parameters, Treatment Protocol, and Device Usage

The Genesis Sleep delivers identical stimulation output to that used in the predicate's study, as verified by comparative testing (e.g., oscilloscope tracings and digital multimeter measurements under 500 Ω, 2 kΩ, and 10 kΩ loads). The treatment protocol and usage are directly comparable, supporting applicability of the predicate's data.

Parameter/ Aspect	Predicate (Modius Sleep) - Pivotal Study	Genesis Sleep	Comparison/ Comment
Waveform	Symmetrical biphasic rectangular	Symmetrical biphasic rectangular	Identical
Frequency	0.25 Hz	0.25 Hz	Identical
Current Intensity	0.1 mA - 1.0 mA (user-adjustable)	0 µA - 1000 µA (0-1 mA, user-adjustable)	Identical range
Pulse Duration	2 seconds	2 seconds	Identical
Primary Phase Duration	4 seconds	4 seconds	Identical
Burst Mode	2 pulses/burst; 0.25 bursts/second; 4-second duration; 50% duty cycle	2 pulses/burst; 0.25 bursts/second; 4-second duration; 50% duty cycle	Identical
ON/OFF Time	2 seconds each	2 seconds each	Identical
Session Length	30 minutes	30 minutes	Identical
Usage Frequency	Daily (28 days UK; 20 days HK over 4 weeks)	Indicated for daily use (up to 30 min/session)	Equivalent; Genesis supports similar

Parameter/ Aspect	Predicate (Modius Sleep) - Pivotal Study	Genesis Sleep	Comparison/ Comment
			home/clinical regimens
Electrode Placement	Bilateral mastoid processes	Mastoid	Identical
Device Usage	At home, while sitting, before sleep; user adjusts intensity via built-in buttons; disposable pads; 16-hour lockout	At home/clinical, while sitting, before sleep; user adjusts via PC-based software; disposable pads; software-monitored overload/shut-off	Equivalent stimulation delivery; minor control difference (PC vs. built-in) does not affect output or protocol; Genesis adds clinical use, but labeling for home use exceeds clinical requirements, and both are prescription-only (no new intended use)
Power Source/Isolation	3.75 V Lithium Polymer Battery; DC:DC transformer	12 V Li-Ion Battery; DC:DC converter	Different voltage but equivalent isolation and safety; output remains identical

Justification for Applicability of Clinical Outcomes, Adverse Events, and Complications

The Genesis Sleep is substantially equivalent to the predicate in all technological characteristics directly impacting stimulation delivery (e.g., waveform, frequency, current, pulse duration, burst mode, output voltage/current under loads, net charge, current/charge/power density - see sections III and IV above). Minor differences (e.g., PC-based controls vs. built-in, aluminum enclosure vs. plastic, non-wearable form factor vs. wearable) do not alter the stimulation output, electrode interface, or user protocol, raising no new questions of safety or effectiveness. Both devices are prescription-only, non-invasive cranial electrotherapy stimulators for chronic insomnia in adults aged 22+.

The predicate's clinical data, from a sham-controlled trial in a comparable population (moderate/severe chronic insomnia, similar demographics), directly applies because the

delivered therapy is identical, ensuring similar efficacy (e.g., ISI reductions approaching clinical meaningfulness) and safety (low rate of minor, self-resolving AEs; no complications). Data generalizability to US populations is supported by comparable baseline ISI scores (18-19 vs. US 17-18), insomnia prevalence (HK 20.7% vs. US/global 10-20%), and lack of evidence for racial/ethnic differences in insomnia presentation/diagnosis.

CES devices collectively demonstrate a class effect of CES for treating anxiety and/or insomnia. However, it cannot be concluded, based on available information alone, that specific CES devices or stimulation parameters are effective for treating anxiety and/or insomnia. As such, individuals using this device should work with the prescribing medical provider to determine the best treatment settings to use.

VII. Conclusion

The two devices have the same intended use and the same main classification. They have most of the same features and technical attributes, including an exact match of their output waveforms. They are used on the same populations. The two products are different in minor ways that do not materially affect their technological basis or use.

Based upon comparisons of regulatory parameters, technical and safety features, comparative performance evaluations, and the applicability of predicate clinical evaluations, the proposed Genesis Sleep device is substantially equivalent to the predicate Modius Sleep (K230826).