February 16, 2021

Neurolief Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2320
Philadelphia, Pennsylvania 19103

Re: K203419
Trade/Device Name: Relivion
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator to Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: November 19, 2020
Received: November 19, 2020

Dear Janice Hogan:

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 Database 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,

Patrick Antkowiak
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)* K203419

Device Name

Relivion®

Indications for Use *(Describe)*

The Relivion® transcutaneous electrical nerve stimulator is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older. It is a prescription device to be self-used at home.

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

RELIVION®

Applicant Name: Neurolief Ltd.
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Contact Person: Michal Kedar-Datel
Clinical & Regulatory Affairs Director
Neurolief Ltd.
Tel: +972-9-3730288

Date Prepared: November 19, 2020

Trade Name: Relivion®

Classification Name: 21 CFR 882.5891 Transcutaneous electrical nerve stimulator to treat headache

Product Code: PCC

Classification: Class II

Classification Panel: Neurology

Predicate Device: CEFALY Technology's Cefaly® Acute (K171446)

Intended Use/Indication for Use:

The Relivion® transcutaneous electrical nerve stimulator is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older. It is a prescription device to be self-used at home.

Device Description:

The Relivion® is an external non-invasive neurostimulator designed for transcutaneous electrical nerve stimulation. The Relivion® headset integrates three pairs of output electrodes which come in contact with the subject's scalp at the forehead and occiput. The electrodes deliver the stimulation pulses produced by the headset's stimulation unit to the subject's scalp. The frontal electrodes stimulate the trigeminal (supraorbital and supratrochlear) nerve branches and the posterior electrodes stimulate the greater occipital nerve branches.

The Relivion® includes single-use replaceable electrode pads that are positioned on-top of the electrodes prior to treatment and are wetted by the user before use, in order to provide proper conductivity between the electrodes and the scalp.

The Relivion® is powered by a rechargeable battery and the headset incorporates an on-board user interface that enables the user to activate/deactivate the device and to adjust the stimulation intensity. Upon treatment activation, the treatment automatically runs and ends after 60 minutes or alternatively, the user can stop the treatment when desired.

The Relivion® can communicate via a low energy Bluetooth link with the Relivion® dedicated mobile application on the user's smartphone. The Relivion® mobile application is optional and it is used to display the device status and provide indications and alerts.

Technological Characteristics:

The Relivion® treats migraines by stimulating the trigeminal and occipital nerve branches by a transcutaneous electrical nerve stimulation. Trigeminal and occipital electrical nerve stimulation induces neuromodulation of these nerve pathways and by that reduces pain associate with migraine and associated symptoms.

The Relivion® includes single-use, replaceable electrode pads that are positioned on-top of the headset electrodes and are wetted by the user before each use. Water releasing covers are located on the outer side of each back occipital electrode and are used to release moisture from the electrode pads to the scalp in order to provide proper electrical conductivity between the electrodes and the scalp.

The Relivion® headset adjusts to various head sizes and contours and can be worn comfortably. The headset includes two flexible arms that penetrate under the hair layers while the headset is worn.

The Relivion® headset incorporates an on-board user interface and can communicate via a low

energy Bluetooth link with the Relivion® dedicated mobile application on the user's smartphone, which displays the device status and provides indications and alerts.

Performance Data:

Neurolief conducted several performance tests to demonstrate that the Relivion® device complies with performance standards and that it functions as intended.

Performance - Bench Testing: The Relivion® device underwent performance testing, including software validation and device verification tests. It was successfully verified that the Relivion® output parameters meet the product's specifications.

Electrical Safety and Electromagnetic Compatibility: in addition, the system was tested per the applicable electrical safety and electromagnetic compatibility standards listed below, and all results were passing.

- IEC 60601-1 Ed. 3.1, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Ed. 4.0, Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-11 Ed. 2.0, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10 Ed. 2.1, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-6 Ed. 3.1, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential Performance - Collateral Standard: Usability
- IEC 62366 Ed. 1.0 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304 Ed. 1.1, Medical device software - Software life-cycle processes

Software Testing: The software was also subject to verification and validation testing, and results demonstrated that the system performed as intended. Cybersecurity risks were also identified and addressed.

Biocompatibility: The Relivion® is a device that contacts intact skin surface for a limited time (<24 hours). The patient-contacting components of the device headset and electrode pads were tested for

cytotoxicity, sensitization, and irritation or intracutaneous reactivity as defined for surface devices in the FDA guidance (2020) and ISO 10993-1: 2009. Based on results of the conducted testing, the final device was determined to be biocompatible for its intended use.
Human Factors Usability Study: The device was also subject to formative and summative Human Factors testing, and results demonstrated that users could complete all essential tasks using the provided labeling with acceptable residual risk.

Performance - Clinical Testing: Two previous versions of Neurolief's device were used in preliminary prospective studies.

The OS-TNS Study was conducted at Meir Medical Center, Israel. The study assessed the safety and efficacy of combined occipital and supraorbital neurostimulation for treatment of migraine. It was approved by the institution's ethics committee on June 5, 2014 and the Israeli Ministry of Health Ethical committee and was concluded in November 2015. This clinical investigation was conducted in accordance with good clinical practice (GCP) as described in ISO 14155. Adults suffering from episodic migraine, aged 21–62 years, were enrolled. Subjects were randomly allocated in a 1:1 ratio to receive active or sham occipital and supraorbital stimulation. The primary endpoint was defined based on relative change (%) in VAS pain score from baseline to end of treatment without using pain medication. 30 patients treated one acute migraine episode with active device (N=15) or sham device (N=15). At the end of treatment there was a significant reduction of the average Pain VAS score in the treatment group vs. an increase in Pain VAS score in the control group (-79.2% vs. +14.9%, respectively; P=0.0002). Pain-free response rates significantly favored the active device at 2-hours (P=0.0031) and at 24-hours (P<0.05) post treatment. Superiority of the active device was also shown for functional disability (P=0.0004) and photophobia (P=0.002). No device-related serious adverse events were recorded.

The SP-301 Study was a prospective, randomized, double-blind, parallel-group, placebo-controlled investigation conducted to evaluate the clinical performance and safety of a self-administered abortive treatment for migraine headache using combined occipital and supraorbital transcutaneous nerve stimulation. The study was conducted at the Laniado Medical Center in Israel and approved by the Laniado Helsinki committee on February 8, 2018. The date of the first patient enrollment was February 22, 2018, and the study concluded on November 2018. This clinical investigation was conducted in accordance with good clinical practice (GCP) as described in ISO 14155. Fifty-five (55) patients were randomized to either the active or placebo groups. To maintain blinding, measures included concealed allocation, use of an identical sham device and the same treatment protocol in all the study stages: device training, self-practice period and treatment period. Additionally, sham stimulation was set to a level well above the sensory threshold to further enhance subject's blinding. Subjects were instructed to use the device during 1 migraine episode within 14 weeks after a practice run in their home. Additionally, subjects were asked not to take any pain medication prior to treatment and until 2 hours post treatment. Mean pain intensity decreased significantly more in the treatment group than in the sham group at 1-hour (group difference: 41.4%; p=0.0002) and at 2-hours (group difference: 32.8%; p=0.0324) and 24-hours (group difference: 36.2%; p=0.0220). Responders rate

was also statistically significantly higher in the treatment group than in the sham group at 1-hour (66.7% vs. 20%, p=0.0014), 2-hours (66.7% vs. 32%, p= 0.0227) and 24-hours (78.3% vs. 48%, p= 0.0401). No Serious Adverse Events (SAEs) were reported throughout the study period. Safety data collected by the research team was recorded and reported to the sponsor. Safety monitoring, including device related assessment was performed by qualified sponsor personnel in consultation with the study PI. Post hoc review was conducted by an independent medical advisor. There were no complaints of unpleasant stimulation sensation during or within 24 hours after the treatment.

The results of these studies demonstrated that combined occipital and supraorbital transcutaneous nerve stimulation (OSTNS) is a safe and highly effective treatment for the treatment of migraine and may serve as a safe, fast acting treatment method.

The device was also subject to a prospective, randomized, parallel-group, sham-controlled clinical trial- the RIME study. The device used in the RIME study is the commercial version for which the company is seeking clearance. The study included 131 patients (109 females and 22 males) having migraine attacks with or without aura. Patients were enrolled at 12 sites in the US and Israel. The study was initiated in November 2018 and concluded in August 2020. The US study sites of the investigation complied with 21 CFR parts 50, 56, and 812 and the OUS clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). To maintain blinding, measures included concealed allocation, use of an identical sham device and the same treatment protocol in all the study stages: device training, self-practice period and treatment period. Additionally, sham stimulation was set to a level well above the sensory threshold to further enhance subject's blinding. These measures were proven to be effective as the blinding assessment revealed that the subjects' feeling regarding the treatment received did not influence the study outcome. Baseline demographics were consistent with the migraine population in terms of age, gender, etc. 83% (109/131) of the participants were females. The mean age was 40.3 years (SD=12.7). The mean age of migraine onset was 18.6 (SD=8.54) years and ranged from 4 to 50. 62.6% (82/131) of the subjects had migraine without aura, 37.4% (49/131) had migraine with aura, 26.7% (35/131) of the subjects were using migraine preventive medication at baseline. Statistical analysis showed no significant differences between the US and Israeli populations.

The primary outcome was the proportion of subjects reporting reduction of migraine headache pain (i.e., pain relief) 2 hours post treatment initiation from severe or moderate to mild or no pain, or from mild to no pain. Pain relief at 2 hours post-treatment was found statistically significantly higher in the active group than in the sham group: 60% of subjects in the active group compared to 37% (p value=0.0180) (mITT) or 36% (p value=0.0135)(PP) in the sham group met the primary endpoint, with similar between-group differences of 23% and 24% (mITT and PP, respectively). All statistical tests for the between-group difference were statistically significant in both populations. Therefore, the study was deemed successful.

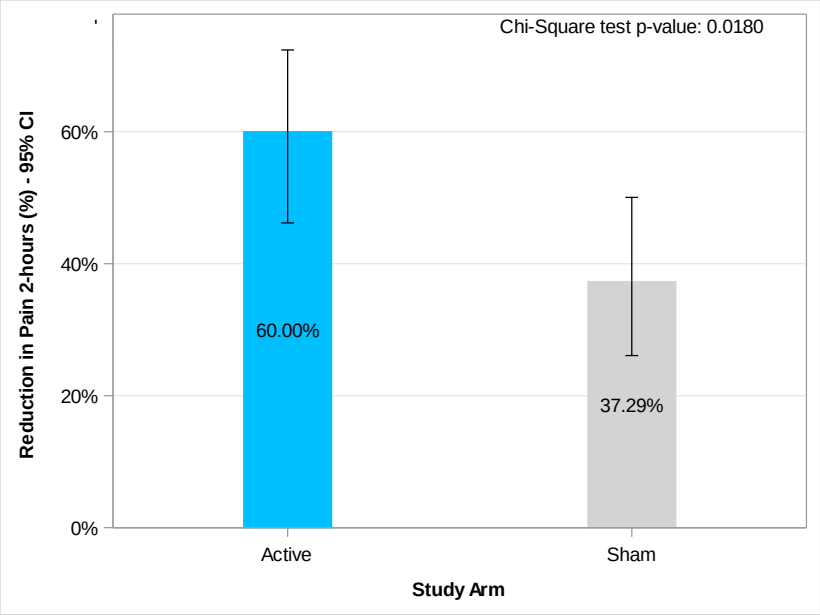

Figure 1: Pain relief 2 Hours Post-Treatment - mITT

Furthermore, the active arm was superior to the sham arm for all 3 secondary endpoints, as follows:

- Pain Freedom rate at 2 hours post-treatment initiation without use of rescue medication (46.00% vs. 11.86% for active and sham arms, respectively, p-value: <0.0001).
- Improvement in MBS 2-hours post-treatment initiation without use of rescue medication (80.56% vs. 60.00% for active and sham arms, respectively, p-value: 0.0466).
- Reduction in pain level - 1-hour post-treatment initiation without use of rescue medication (-0.6 (-28.7%) vs. -0.3 (-14.4%) for active and sham arms, respectively, p-value: 0.0121).

In addition, the active arm was superior to the sham arm in the following additional parameters:

- Complete MBS Freedom 1- and 2-hours post-treatment initiation without use of rescue medication.
- Pain Freedom at 1-hour post-treatment initiation without use of rescue medication.
- Pain and MBS Relief at 1- and 2-hours post-treatment initiation without use of rescue medication.
- Complete symptoms Free (Pain and MBS)- 1- and 2-hours post-treatment initiation without use of rescue medication.
- Sustained 2-24 hours headache Pain Relief and Pain Freedom without use of rescue medication.
- Pain Relief and Pain Freedom consistency of response across multiple treated episodes.

With respect to safety, safety monitoring, including device related assessment was performed by qualified sponsor personnel in consultation with the study PI and the medical advisor. In the ITT analysis set, 21 AE's were reported in 10 subjects, 8 in the active arm (incidence: 11.94%, 8/67), and 2 in the sham arm (incidence: 3.13% ,2/64). None of the adverse events were serious, 7 AE's were considered moderate (4 in the active arm and 3 in the sham arm), and the other 14 were mild. 16 AE's were considered as at least possibly related to the study device (7 in 5 subjects randomized to active arm; 9 in 2 subjects in the sham arm). All the reported AEs were fully reversible and resolved without intervention. The nature of the observed events in the active group were anticipated and very similar to other nerve stimulators for migraine, including adverse events that are directly related to the neuromodulatory action of the device such as transient scalp numbness sensation, tingling and twitching. The rate and severity of events was as anticipated and similar to other previously cleared devices. An initial device malfunction resulted in exclusion of the first 50 cases from the above analysis. Because the malfunction resulted in failure to deliver stimulation, these patients were not analyzed for efficacy but were analyzed for safety, and the results were consistent with those reported for the ITT population.

Although COVID-19 resulted in interruption of study enrollment and early termination, FDA guidance was followed in the completion and analysis of study results in light of the pandemic and met the study hypothesis, as presented above, supporting substantial equivalence.

Substantial Equivalence:

The following table compares the Relivion® device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 1: Neurolief, Ltd.'s Relivion® Substantial Equivalence

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
General Characteristics			
510(k) number	Pending	K171446	N/A
Classification	21 CFR § 882.5891	21 CFR § 882.5891	Same
Product Code	PCC	PCC	Same
Product Class	Class II	Class II	Same
Regulation Name	Transcutaneous Electrical Nerve Stimulator to Treat Headache	Transcutaneous Electrical Nerve Stimulator to Treat Headache	Same
Indications for Use	The Relivion® transcutaneous electrical nerve stimulator is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older. It is a prescription device to be self-used at home.	Cefaly® Acute is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older.	Same (Both devices are intended for self-administered, at home use)
Technology	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator	Same
Invasiveness	Non-Surgical	Non-Surgical	Same
Electrode Locations	Forehead and Occiput	Forehead	Similar (Forehead location is the same for both devices; addition of occiput location does not raise new questions—see below.)

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
Nerves over which electrodes are placed	Supratrochlear and supraorbital branches of the trigeminal nerve bilaterally and the occipital nerves	Supratrochlear and supraorbital branches of the trigeminal nerve bilaterally	Similar (Relivion® treats the occipital nerves in addition to the trigeminal nerve, but the therapeutic effect is the same)
Energy	Electric	Electric	Same
Power Source	Rechargeable Li-Po 3.7 V Battery	Rechargeable LiPo 3.7 V battery	Same
Software-controlled	Yes, 1 fixed program	Yes, 1 fixed program	Same
Constant Current	Yes	Yes	Same
Constant Voltage	No	No	Same
Software Function	Controls the output of the device and device indicators	Controls the output of the device and device indicators	Same
Timer Settings	Yes	Yes	Same
Patient override control method	On/Off button	On/Off button	Same
Button Types	On/Off Button and buttons to adjust intensity of electrical stimulus	On/Off Button and buttons to adjust intensity of electrical stimulus	Same
Functional features	Visual and auditory indicators inform the user when the device is on vs. off and help them troubleshoot if it is not working properly (e.g., indicates if device is active/non-active, low battery indication and if electrical connection between device and skin is unacceptable)	Visual and auditory indicators inform the user when the device is on vs. off and help them troubleshoot if it is not working properly (e.g., indicates if device is active/non-active , low	Same

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
		battery indication and if electrical connection between device and skin is unacceptable)	
Bluetooth Capable	Yes	No	Different (Relivion® includes a mobile app and Bluetooth capability, but these features do not alter the therapeutic effect)
Associated mobile application to display device status, treatment duration, and battery status	Yes	No	
Max leakage current	None (battery operated)	None (battery operated)	Same
Electrodes	Relivion® electrode	Cefaly® electrode	Similar (Each device uses its own designated electrode, but the components perform similarly, as established by bench testing)
Indicator display: Unit functioning	Yes	Yes	Same
Low battery indicator	Yes	Yes	Same
Standards: IEC 60601-1	Yes	Yes	Same
IEC 60601-1-2	Yes	Yes	Same
IEC 60601-1-6	Yes	Yes	Same
IEC 60601-1-11	Yes	Yes	Same

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
IEC 60601-2-10	Yes	Yes	Same
IEC 62366	Yes	Yes	Same
Weight	90 gr	12 gr	Different (The difference in weight is not clinically relevant to the treatment)
Dimensions	209mm x 128mm x 39mm	55 mm x 40 mm x 15 mm	Different (The difference in size is not clinically relevant to the treatment)
Housing materials	Plastic PA + Silicone	Plastic PC	Similar (Manufacturing the device housing from Plastic PA and Silicon rather than Plastic PC does not raise different questions of safety and effectiveness)
Maximum Time Device Used	60 minutes	60 minutes	Same
Net Charge (µC) per pulse	0	0	Same

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
Pulse Duration (µsec)	850	505	Similar (Differences in the stimulation parameters were evaluated in the clinical testing, and the results confirmed that the devices have equivalent safety and efficacy performance)
Frequency (Hz)	80	100	
Maximum output voltage (V): @500 ohms @2000 ohms @10000 ohms	3 front electrodes / 6 back electrodes 12 front electrodes / 24 back electrodes 60 front electrodes / 100 back electrodes	8 32 60	
Maximum output current (mA): @500 ohms @2000 ohms @10000 ohms	6 front electrodes /12 back electrodes 6 front electrodes /12 back electrodes 6 front electrodes /10 back electrodes	16 16 6	
Max Phase Amplitude	6 mA front electrodes/ 12 mA back electrodes; with a load of a 4.7 uF capacitor parallel with 2.2K ohms resistance	16 mA with a load of a 4.7 uF capacitor parallel with 2.2K ohms resistance	
Maximum phase charge (µC) @500Ω	4.8	4	
Maximum Current Density, (mA/cm², r.m.s.) @500Ω	1.93 front electrodes/ 2.78 back electrodes	2.37	
Maximum Average Power Density, (W/cm²) @500Ω	0.0000116 front electrodes / 0.000034 back electrodes	0.000047	
Maximum Average Current (average absolute value, mA) @500Ω	0.38 front electrodes / 0.76 back electrodes	0.8	
Phase rise time	5 µS	2 µS	
Modulation Options Amplitude Frequency Duration	0- 12 mA Fixed @ 80 Hz 330- 400 µS	0-16 mA Fixed @ 100 Hz Fixed @ 250 µS	
Phase decay time	2 µS	2 µS	Same

Parameter	Neurolief Ltd.'s Relivion® (Subject Device)	CEFALY Technology's Cefaly® Acute (Predicate Device)	Comparison
Ramp Modulations **Ramp Up** **Ramp Down**	 Manually Manually	 14 minutes 1 minute	Different (Relivion®'s use of manual ramp modulation does not raise different questions of safety and effectiveness)

As described in the comparison table above, the subject Relivion® and the predicate Cefaly® Acute (K171446) share the same intended use and similar indications, technological characteristics, and same principles of operation. The minor differences in the technological characteristics do not alter the overall therapeutic effect of the device. Any differences between the Relivion® and its predicate (K171446) were carefully evaluated through performance testing. The Relivion® device underwent performance testing, including bench testing, clinical testing, software validation testing, electrical safety according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2 and other tests. These performance tests confirmed that the Relivion® complies with the same special controls and the same consensus and performance standards, on which FDA based its clearance of the Cefaly® Acute (K171446), and demonstrated that the differences in the technological characteristics between the subject and predicate device do not adversely impact performance and that the subject Relivion® is substantially equivalent to its predicate device (K171446).

Conclusions:

Therefore, based on the same intended use and similar indications, technological characteristics, and same principles of operation, the Relivion® device is substantially equivalent to its predicate device.