June 21, 2022

SOMNOmedics GmbH
Timo Gehring
Regulatory Affairs Manager
Am Sonnenstuhl 63
Randersacker, 97236
Germany

Re: K212325
Trade/Device Name: EEG-acp
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB

Dear Timo Gehring:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 15, 2022. Specifically, FDA is updating this SE Letter to reflect an administrative error made in the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Heather Dean, OHT5: Office of Neurological and Physical Medicine Devices, 240-402-9874, Heather.Dean@fda.hhs.gov.

Sincerely,

Heather L. Dean -S

Heather Dean, PhD.
Assistant Director, Acute Injury Devices Team
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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

June 15, 2022

SOMNOmedics GmbH
Timo Gehring
Regulatory Affairs Manager
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Randersacker, 97236
Germany

Re: K212325
Trade/Device Name: EEG-acp
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB
Dated: June 8, 2022
Received: June 13, 2022

Dear Timo Gehring:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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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)*
K212325

Device Name
EEG-acp

Indications for Use *(Describe)*
EEG adhesive conductive paste (hereafter EEG-acp) is intended for use in clinical and research EEG recordings from humans under professional guidance. EEG-acp is an electroconductive paste which should be used in combination with EEG cup electrodes on the scalp.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Manufacturer's Name:	SOMNOmedics GmbH Am Sonnenstuhl 63 97236 Randersacker, Germany
Official Correspondent:	Dr. Marc Paul Regulatory Affairs
Telephone Number:	+49 931 359094-0
Fax Number:	+49 931 359094-49
Date of preparation:	July 23, 2021
Proprietary Name:	EEG-acp
Common Name	Electrode cream
Classification Name:	Electroconductive Media (21 CFR 882.1275, Product Code GYB)
Device Class:	Class II
Product Code:	GYB
Classification Regulation:	21 CFR 882.1275 Electroconductive Media
Predicate Device:	SAC2 – Electrode cream (K192606)

Device description

EEG adhesive conductive paste (hereafter EEG-acp) is intended for use in clinical and research EEG recordings from humans (from the age of 2) under professional guidance. EEG-acp is an electroconductive paste which should be used in combination with EEG cup electrodes on the scalp. It acts as a conductor between the scalp and the cup electrodes to reduce impedance between the electrode surface and the skin. The reduction in impedance facilitates better recording of the signal. It is intended to be used for up to 10 hours after application to healthy, intact skin. After drying, it is self-adhesive and can be washed off with water.

The cream is provided non-sterile and in a 100g aluminum tube. It is white and has no adverse smell. Its texture is smooth and creamy directly after withdrawal from the tube, and solid after drying.

EEG-acp is intended to be used as an electroconductive medium between the electrode and the patient's skin, i.e., it amplifies the electrical signal and thereby improves the electrophysiological recording. The high salt content of the cream is responsible for its conductive properties. Its impedance is -1.9 kΩ and its conductivity is 20 mS/cm.

The cream consists of the following substances:

EEG-acp Electrode Cream (K212325)

Allantoin, Bentonite, Glycerin, Lactate, Panthenol, PEG-40, Phenoxyethanol, Polyquaternium-10, Sodium Chloride, Sodium Hydroxide, Skin protection solution, Talcum, Water, Zinc oxide

Ingredients such as Allantoin, Polyquaternium-10 and Panthenol are used in a large variety of pharmaceutical and cosmetical drugs for skin care/protection and healing. In the EEG-acp these ingredients are included to reduce the occurrence and severity of occasionally occurring adverse effects such as itching, skin irritation and hypersensitive skin reactions and thereby improve the cream's safety. The pH (6-7.5) is adjusted to a more skin-neutral pH, contributing to a less stressful application to the skin.

The shelf life of EEG-acp is two years if stored at a cool place (59 to 86 F) and protected from sunlight. During this period, it will not crystallize, flocculate, nor change its color or smell.

Indications for use

EEG adhesive conductive paste (hereafter EEG-acp) is intended for use in clinical and research EEG recordings from humans under professional guidance. EEG-acp is an electroconductive paste which should be used in combination with EEG cup electrodes on the scalp.

Technological characteristics

Technical properties are substantially equivalent between the subject and predicate device. Both creams are provided non-sterile and are salt-based, non-irritating and non-toxic. They become adhesive and form a solid connection between the electrode and the skin after drying.

EEG-acp and SAC2 are conductive creams provided in 100g aluminum tubes.

Both devices are water-based, use salts as conductive material (SAC2 contains additionally KCl), contain preservatives and thickening agents. There is no permissible exposure limit (PEL) for either of the devices.

The subject device contains additional ingredients such as Allantoin and Dexpanthenol. All of these substances are employed in a large variety of pharmaceutical drugs and cosmetical products for skin care, skin protection and healing. In the subject device, these ingredients are included to reduce the frequency and severity of occasionally occurring adverse effects such as itching, skin irritation and hypersensitive skin reactions and thereby improve the cream's safety.

Impedance and conductivity as the most relevant performance characteristics of the proposed intended use of EEG-acp are equivalent for SAC2 and EEG-acp. The pH of the predicate device is alkaline, whereas the subject device's pH is acidic to neutral. Acidic skin care products are considered to be preferable for patients with skin diseases because of their favorable tolerability profile and bacteria regulating properties (Schmid-Wendner and Korting, 2006)[1]. The pH difference has therefore no impact on the safety and the effectiveness of the subject device and does not raise any new concerns.

Substantial Equivalence

EEG-acp is equivalent to the predicate device as presented in table 5-1.

It has been shown in this 510(k) submission that the differences between EEG-acp and its predicate device SAC2 do not raise any concerns regarding the safety and effectiveness of EEG-acp. The subject device is substantially equivalent to the predicate device, because it has the same intended use, similar technological characteristics and the same performance characteristics as the previously cleared predicate device SAC2.

Table 5-1: Substantial Equivalence

Trade name	**EEG-acp (new device)**	**SAC2 Electrode Cream (predicate)**	**Discussion of differences**
Manufacturer	**SOMNOmedics GmbH**	**Spes Medica S.r.l.**	
510(k) number	**K212325**	**K192606**	
Product code	**GYB**	**GYB**	
Regulation name	Electroconductive Media	Electroconductive Media	Same as predicate device
Regulation number	882.1275	882.1275	Same as predicate device
Indications for use	EEG adhesive conductive paste (hereafter EEG-acp) is intended for use in clinical and research EEG recordings under professional guidance. EEG-acp is an electroconductive paste which should be used in combination with EEG cup electrodes on scalp.	SAC2 is intended for use in clinical and research EEG/EP recordings from humans. It is used with external electrodes as the conductor between the scalp and recessed electrodes to reduce impedance between the electrode surface and the skin.	The indications for use are in principle the same as for the predicate device. EEG-acp specifies the exact type of electrodes (“cup electrodes” instead of more generally ”recessed electrodes”) and the predicate allows also its use for EP recordings.
Use environment	Electrophysiological	Electrophysiological	Same as predicate device
Intended user	Trained medical personnel	Neurologists	Intended users of EEG-acp are stated in more general terms than the predicate device. This is acceptable because electrodes are typically not only applied by the neurologist, but also their medical staff, if they are trained accordingly. No new questions of safety or effectiveness are raised.
Intended patient population	Adults and children older than 2 years	Adults and children	The device is intended for children older than 2 years as a precaution to protect the sensitive

			skin of neonates and infants. No negative impact on the safety or effectiveness of the subject device.
Intended use time	< 10 hours	>24h, < 30 days	Shorter than the predicate device; no negative impact on safety or effectiveness of the subject device.
Body contact	Topically on intact skin	Topically on intact skin	Same as predicate device
Thickening agent	Hydroxyethylcellulose, Glycerin	Carboxymethylcellulose, Glycerol	Agents with similar properties. Texture, density and viscosity is the same as the predicate device.
Preservative	Phenoxyethanol	Phenoxyethanol, Ethylhexylglycerin	The predicate device contains an additional preservative to expand its shelf life for an additional year. No new questions regarding safety or effectiveness are raised.
Conductive material	Salt (NaCl)	Salts (NaCl and KCl)	Only Sodium Chloride is used in the subject device. No difference on effectiveness of the device because the conductivity is the same. No new questions regarding safety are raised.
Chemical safety	No OSHA PEL	No OSHA PEL	Same as predicate device
Biocompatibility	Evaluation in accordance with ISO 10993-1	Evaluation in accordance with ISO 10993-1	Same as predicate device
Cytotoxicity	Yes	Yes	Same as predicate device
Irritation	Yes	Yes	Same as predicate device
Sensitization	Yes	Yes	Same as predicate device
Single Use	Yes	Yes	Same as predicate device
Sterilization	Provided non-sterile	Provided non-sterile	Same as predicate device
Shelf life	2 years	3 years	Shorter than the predicate device. Shelf life is clearly communicated on the device via the “Best before” symbol and the unambiguous date of the end of shelf life. No new questions

			regarding safety or effectiveness are raised.
Impedance	0.3 ± 0.1 kOhm	50 ± 10 Ohm	Higher than the predicate device. Differences are due to different test setup. Impedance of the subject device when placed on skin is equivalent to the predicate devices. No new questions regarding safety or effectiveness are raised.
Conductivity	20 mS/cm	20 mS/ cm	Same as predicate device
Time to dry	> 15 min	> Not Publicly Available	No new questions regarding safety or effectiveness are raised.
pH range	6 – 7.5	8-10	The subject device's pH is neutral whereas the predicate device's is more basic. pH is adjusted with lactate to be closer to the natural skin pH (4.7-5.75). No new questions of safety or effectiveness are raised.
Weight	100g per tube	100 g per tube	Same as predicate device
Packaging	Aluminum tube	Aluminum tube	Same as predicate device
Characteristics	Salt base Non-irritating Non toxic White color adhesive	Salt base Non-irritating Non toxic Light-Grey color adhesive	Same as predicate device

Summary of Performance Testing – Biocompatibility

Biocompatibility has been evaluated for the EEG-acp in accordance with ISO 10993-1:2018.

The cream has contact with intact skin for < 24h.

The following tests for biocompatibility were performed:

- **ISO 10993-5:** Cytotoxicity
  in vitro Skin Irritation (Human Skin Model Test)
- **ISO 10993-10:** Acute Dermal Irritation/ Corrosion
  Irritation/ Skin Sensitization
  Guinea Pig Maximization Test

Chemical characterization of the cream was not performed, as the exact chemical composition and chemical properties of all ingredients is known.

Performance Testing – Bench Testing

Performance characteristics of EEG-acp were verified for:

- **Impedance**

  Impedance and conductivity of the device was measured to confirm that it is equivalent to the predicate device. It is an effective electroconductive medium to reduce the impedance of EEG cup electrodes.

- **Qualitative characteristics**

  Color, odor, adhesiveness and time to dry are as specified and equivalent to the predicate device.

- **Shelf-life**

  The indicated shelf life of 2 years was validated by accelerated aging testing in accordance with ASTM F1980-16.

  Pass/fail criteria were defined at the beginning of the test (color, consistency, impedance). The cream was found to meet these criteria and to confirm the shelf life.

Conclusion

Results of performance testing demonstrate that EEG-acp meets the specified performance and design characteristics. It is safe for use and effective. The performance data demonstrate and support the substantial equivalence of EEG-acp with its predicate, SAC2 Electrode cream, with regards to safety, effectiveness and performance.