December 1, 2021

Spes Medica S.r.l
Giorgio Facco
Quality Assurance & Regulatory Affairs
Via Europa-Zona industriale
Battipaglia, 84091
Italy

Re: K212326
Trade/Device Name: AC Cream - Conductive paste
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: October 18, 2021
Received: November 10, 2021

Dear Giorgio Facco:

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 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

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)*
K212326

Device Name
AC Cream - Conductive paste

Indications for Use *(Describe)*
AC Cream - Conductive paste 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.

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.

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510(k) Summary

K212326

Manufacturer's Name:	Spes Medica S.r.l. via Europa (Zona Ind.le), 84091 Battipaglia (SA) – Italy
Official Correspondent:	Giorgio Facco Quality Assurance and Regulatory Affairs
Telephone Number:	0039 0828 614191
Fax Number:	0039 0828 341788
Trade Names:	AC Cream - Conductive paste
Common or Usual Name:	AC Cream - Conductive paste
Classification Name:	Media, Electroconductive
Device Class:	Class II
Product Code:	GYB
Classification Regulation:	882.1275
Predicate Device:	SAC2 – Electrode cream 510(k) number: K192606
Device Description:	AC Cream - Conductive paste 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. AC Cream - Conductive paste is provided in a PE jar (25g, 50g 100g, 250g) or in an aluminum tube of 100g.

It's characterized by pale yellow colour, no crystallization, no flocculation, bright.
AC Cream - Conductive paste function is of conductor between the electrode used and the patient's skin and of getting the impedance lower for a better recording of the signal. AC Cream - Conductive paste is for external use with recording electrodes only.
AC Cream - Conductive paste is made of powders, Potassium Chloride and Sodium Chloride as conductors, combined with thickening agents and humectants, all in an aqueous solvent.

The composition is the following:
Water, Ceteareth-20, Glycerol, Propylene Glycol, Bentonite, Sodium chloride, Potassium chloride, Calcium carbonate, Polysorbate 20, Phenoxyethanol, Ethylhexylglycerin

The pH range is 6÷8, and Impedance at 10Hz is 120± 25 Ohm.
The mean impedance after 7 days use, considering the worst values detected, is around 480 ± 10 Ohm.
The Conductivity is 20 mS/cm
Shelf life of AC Cream - Conductive paste is 3 years if stored properly in the closed packaging, kept away from the sunlight and within the limit temperature

Intended Use:

AC Cream - Conductive paste 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.

Technological Comparison:

AC Cream - Conductive paste is a conductive electrode paste contained in a PE jar or aluminum tube.
The characteristics of AC Cream - Conductive paste are substantially equivalent to the predicate device. No new questions of safety or effectiveness are raised.
AC Cream - Conductive paste employs the same technological characteristics as the predicate device with just different appearance: the predicate device is a cream instead AC Cream - Conductive paste is a paste.

To support the technological comparison the ingredients, pH, impedance, weight and conductivity of the AC Cream - Conductive paste were evaluated internally and compared to the predicate device.
Both devices are water based with salt as conductive material and with thickening agents (Glycerin is used for both the products).

The impedance of the AC Cream - Conductive paste is higher than the predicate device: the impedance evaluated by Spes Medica is 120 ± 25 Ohm. The pH of the AC Cream - Conductive paste is between 6 and 8, lower than the Predicate Device.

The predicate device is a cream while the AC Cream - Conductive paste is a paste, the different texture was created just to allow the user to choose what he/she prefers to use during the exam (cream or paste). It's just different way of usability of the product.

Substantial Equivalence:

AC Cream - Conductive paste is equivalent to the device cleared under K192606 as is presented below in Table.

It has been shown in this 510(k) submission that the differences between AC Cream - Conductive paste and the predicate device SAC2 – Electrode Cream do not raise any questions regarding its safety and effectiveness. The AC Cream - Conductive paste device is substantially equivalent to the predicate device as it has the same intended use and similar technological characteristics as the previously cleared predicate devices.

Manufacturer	**Spes Medica S.r.l.**	**Spes Medica S.r.l.**	**Discussion Differences**
Trade Name	**AC Cream - Conductive paste**	**SAC 2 – Electrode Cream**	
510(k) number	***K212326***	***K192606***	
Product Code	**GYB**	**GYB**	
Indications for use	AC Cream - Conductive paste 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	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	Same as predicate device
Regulation Name	Media, Electroconductive	Media, Electroconductive	Same as predicate device
Regulation Number	882.1275	882.1275	Same as predicate device
Environment of use	Electrophysiological	Electrophysiological	Same as predicate device
Intended user	Neurologists	Neurologists	Same as predicate device
Target patient	Adult and children	Adult and children	Same as predicate device
Where used	Topically on intact skin	Topically on intact skin	Same as predicate device
Conductive material	Salts (Sodium chloride (NaCl) and Potassium chloride (KCl))	Salts (Sodium chloride (NaCl) and Potassium chloride (KCl))	Same as predicate device
Thickening agent	Glycerol, Bentonite, Propylene Glycol	Glycerol, CarboxyMethylCellulose	Equivalent to the predicate. Glycerol is used both for AC Cream – Conductive paste and for predicate device. The other components (Bentonite, Propylene Glycol for AC Cream – Conductive paste and CarboxyMethylCellulose for SAC2) have the same function of thickening agents but for AC Cream the chosen components are not the same as SAC2 because it is wanted a different final texture (AC Cream – conductive paste is less viscous and more sticky).

			The different use of ingredients does not affect the functional characteristics of the product (electroconductive media) The different texture, due to the use of different components but with the same function, allows the final user the choice the preferred products according to its needs. No new questions of safety or effectiveness are raised.
Preservative	Phenoxyethanol, Ehylhexylglycerin	Phenoxyethanol, Ehylhexylglycerin	Same as predicate device
Opacifying	Calcium carbonate	Talc, Celite	The ingredients are different but have the same function. Not the same ingredients have been used as it is wanted a less opaque and pale yellow (AC Cream – conductive paste) paste. The predicate device is gray colored and more opaque. The different use of ingredients does not alter the functional characteristics of the product (electroconductive media) but act only on the aesthetic aspect (color and opacity). Also in this case the final user can choose the preferred products according to its needs.
Sterilization method	Provide non sterile	Provide non sterile	Same as predicate device
Shelf-life	3 years	3 years	Same as predicate device
Chemical Safety	No OSHA PEL	No OSHA PEL	Same as predicate device
Biocompatibility	Test in accordance with ISO 10993	Test in accordance with ISO 10993	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
pH range	6÷8	8÷10	The pH of AC Cream – Conductive cream final formulation (6 – 8, neutral) is different from the pH of SAC2 final formulation (8 – 10, basic) due

			to the different components and different percentage of components. The measured pH of the final product is an intrinsic characteristic of the paste but is not relevant considering the functionality of the product. The functionality and effectiveness are not affected by pH. The functionality of the product is given by the salts ("conductive material") present in both products. Furthermore, the skin has a good tolerance for both the pH, also according to the positive biocompatibility tests Considering the lines above, no new question about safety and effectiveness of the subject device are raised
Impedance	120 ± 25 Ohm	50 ± 10 Ohm	AC Cream - Conductive paste has a higher impedance, but no new question of safety or effectiveness are raised as the AC Cream - Conductive paste impedance is lower than the maximum limit of 2000 Ω according to the ANSI/AAMI EC12:2000/(R)2015
Conductivity	20mS/cm	20mS/cm	Same as predicate device
Characteristics	Salt Base Non-irritating Non toxic	Salt Base Non-irritating Non toxic	Same as predicate device
Weight	100g per tube 25g, 50g, 100g, 250 g per jar	100g per tube	No differences for the tube. The different packaging (jar) was made to give to the users an alternative way of use according to its needs. Considering that, no new questions of safety or effectiveness are raised.
Packaging	Aluminum tube PE jar	Aluminum tube	No differences for the tube. AC Cream - Conductive paste can also be packaged in a jar, this is a further change for the

			user to choose the packaging according to its needs. Anyway, both materials are validated.

Summary of Performance Testing-Biocompatibility

Spes Medica AC Cream - Conductive paste is no invasive product, the Biocompatibility Evaluation testing summarized below was conducted on AC Cream - Conductive paste to demonstrate compliance of this product to the following standards:

- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity,
- ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Component Name	Type of contact			Material
	Skin	Blood	Tissue	
Paste	Y	N	N	Water, Ceteareth-20, Glycerol, Propylene Glycol, Bentonite, Sodium chloride, Potassium chloride, Calcium carbonate, Polysorbate 20, Phenoxyethanol, Ethylhexylglycerin

Contact duration: >24h, <30days

Performance Testing - Bench Testing

Performance Testing was performed on device characteristics of Spes Medica AC Cream - Conductive paste. This performance mechanical testing consisted of

- **Aging test**
  The aim of this test was to validate the shelf life of 3 years through an accelerated aging procedure according to the ASTM F1980-16 “Standard guide for accelerated aging of sterile barrier system for medical devices”).
  Pass/fail criteria was fixed at the beginning of the test. All the result of the parameters evaluated (colour, crystallization, flocculation, brightness, pH, impedance) comply according to the pass/fail criteria: AC Cream - Conductive paste should be characterized by pale yellow colour, no crystallization, no flocculation, bright.
  Also, the instant impedance was evaluated for the whole shelf life (accelerating aging) of the product and was found out to comply according to the ANSI/AAMIEC12:2000/(R)2015. Results in the table below:

Primary packaging	Mean instant impedance after 0	Mean instant impedance after 28	Mean instant impedance after 56	Mean instant impedance after 84 days

	days of shelf life (accelerating aging)	days of shelf life (accelerating aging)	days of shelf life (accelerating aging)	of shelf life (accelerating aging)
PE jar	101 Ohm	108 Ohm	126 Ohm	144 Ohm
Aluminum tube	104 Ohm	118 Ohm	101 Ohm	108 Ohm

- **Long term conductivity**
  The aim of this test was to evaluate the electrical performances (in terms of AC Impedance and DC Offset Voltage) of the product AC Cream - Conductive paste over time.
  Pass/fail criteria were set at the beginning of the test according to ANSI/AAMIEC12:2000/(R)2015: the DC Offset voltage should not exceed 100mV and AC Impedance should not exceed 2000 Ohm.
  The parameters of AC Impedance and DC Offset Voltage comply according to the ANSI/AAMIEC12:2000/(R)2015 limits even after 7 days testing.

Spes Medica AC Cream - Conductive paste is tested internally for pH, impedance on a regular basis

Performance Testing - Clinical Testing

The subject device AC Cream – Conductive paste does not need clinical testing, so no clinical testing has been made.

Conclusion

All performance testing conducted as outlined above demonstrate that the device meets the performance and design specifications.
The device is as safe, as effective, and is substantially equivalent to the legally marketed device predicate device.