January 17, 2020

Spes Medica S.r.l.
Giorgio Facco
Regulatory Affairs and Quality Assurance
Via Europa - zona industriale
Battipaglia (SA), 84091 Italy

Re: K192606
Trade/Device Name: SAC2 - Electrode Cream
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: September 16, 2019
Received: September 20, 2019

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,

For Vivek Pinto, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192606

Device Name
SAC2 – Electrode cream

Indications for Use *(Describe)*
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.

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

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: SAC2 – Electrode cream

Common or Usual Name: Media, Electroconductive

Classification Name: Electroconductive Media

Device Class: Class II

Product Code: GYB

Classification Regulation: 882.1275

Predicate Device: Tech Dots – Adhesive and Conductive Gel
510(k) number: K190050

Device Description: 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.

SAC2 is provided in an aluminum tube of 100g.
It's characterized by light grey colour, no crystallization, no flocculation, no adverse smell, opaque.
SAC2 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. SAC2 is for external use with recording electrodes only.
SAC2 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, Talc, Celite, Glycerol, CarboxyMethylCellulose, Sodium chloride, Potassium chloride, Phenoxyethanol, Ehylhexylglycerin

The pH range is 8÷10, and Impedance at 10Hz is 50 ± 10 Ohm.

The Conductivity is 20 mS/cm
Shelf life of SAC2 is 3 years if stored properly in the closed aluminum tube kept away from the sunlight.

Intended Use:

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.

Technological Comparison:

SAC2 is a conductive electrode cream contained in an aluminum tube.
The characteristics of SAC2 are substantially equivalent to the predicate device. No new questions of safety or effectiveness are raised.
SAC2 employs the same technological characteristics as the predicate device with just different appearance: the predicate device is a gel instead SAC2 is a cream.

To support the technological comparison the ingredients, pH, impedance, weight and conductivity of the SAC2 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 SAC2 is comparable to the predicate device: the impedance evaluated by Spes Medica is 50 ± 10 Ohm. The pH of the SAC2 is between 8 and 10, higher than the Predicate Device.

The predicate device is a gel while the SAC2 is a cream, the different texture was created just to allow the user to choose what he/she prefers to use during the exam (cream or gel). It's just different way of usability of the product.

Substantial Equivalence:

SAC2 is equivalent to the device cleared under K190050 as is presented below in Table.

It has been shown in this 510(k) submission that the differences between SAC2 and the predicate device Tech Dots do not raise any questions regarding its safety and effectiveness. The SAC2 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	**SAC 2**	**Tech Dots**	
510(k) number	***New Device***	**K190050**	
Product Code	**GYB**	**GYB**	
Indications for use	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	Tech Dots are intended for use in clinical and research EEG/EP recordings from humans. They are 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 (NaCl and KCl)	Salt (NaCl)	Same as predicate device
Thickening agent	CarboxyMethylCellulose, Glycerol	Sodium Acrylates Copolymers, Glycerin	Equivalent to predicate device
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
Preservative	Phenoxyethanol, Ehylhexylglycerin	No preservative	SAC2 contains preservatives which prevent the spread of bacteria when the tube is opened. The predicate device has a different packaging so preservatives are not necessary. In both cases the products results to be biocompatible, so for SAC2 no new questions of safety or effectiveness are raised.

Manufacturer	Spes Medica S.r.l.	Spes Medica S.r.l.	Discussion Differences
Trade Name	**SAC 2**	**Tech Dots**	
510(k) number	***New Device***	**K190050**	
Product Code	**GYB**	**GYB**	
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	8÷10	4÷5	The pH of SAC2 is basic, the pH of the predicate device is acid but in both cases the products results to be biocompatible, so for SAC2 no new questions of safety or effectiveness are raised.
Impedance	50 ± 10 Ohm	80 ± 10 Ohm	SAC2 has an impedance of 50±10 Ohms which is lower than the impedance of the predicate device. This can be consider as an improvement as lower impedance means better signal during recording and more conductivity. Considering that, no new questions of safety or effectiveness are raised.
Conductivity	20mS/cm	2mS/cm	SAC2 results to have an higher value of conductivity comparing to the predicate, this is an advantage (according to the intent of use) as the cream results to be more

Manufacturer	Spes Medica S.r.l.	Spes Medica S.r.l.	Discussion Differences
Trade Name	**SAC 2**	**Tech Dots**	
510(k) number	***New Device***	**K190050**	
Product Code	**GYB**	**GYB**	
			conductive than the predicate device. Considering that, no new questions of safety or effectiveness are raised.
Weight	100g per tube	0.14 ± 0.01 g per Dot	Different packaging and shape The different packaging was made to give to the users an alternative way to conduct exams. The predicate device is packaged as a pre-set quantity for one electrode (0.14±0.001g per dot), with SAC2 the user can decide itself the quantity to apply with one electrode. Considering that, no new questions of safety or effectiveness are raised.
Characteristics	Salt Base Non-irritating Non toxic	Salt Base Non-irritating Non toxic	Equivalent to predicate device
Packaging	Aluminum tube	Aluminum/PET/PE	Different ways of packaging. Both materials are validated.

Summary of Performance Testing-Biocompatibility

Spes Medica SAC2 is no invasive product, the Biocompatibility Evaluation testing summarized below was conducted on SAC2 to demonstrate compliance of this product to the following standards:

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- 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	
Cream	Y	N	N	Water, Talc, Celite, Glycerol, CarboxyMethylCellulose, Sodium chloride, Potassium chloride, Phenoxyethanol, Ehylhexylglycerin

Contact duration: >24h, <30days

Performance Testing-Bench Testing

Performance Testing was performed on device characteristics of Spes Medica SAC2. 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 and all the result of the parameters evaluated (colour, crystallization, flocculation, brightness, pH, impedance) comply according to the pass/fail criteria: SAC2 should be characterized by light grey colour, no crystallization, no flocculation, opaque.
  Also, the impedance was evaluated and was found out to comply according to the ANSI/AAMIEC12:2000/(R)2015.

- **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 SAC2 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 SAC2 are tested internally for pH, impedance on a regular basis

Conclusion

All performance testing conducted as outlined above demonstrate that the device meets the performance and design specifications.