October 18, 2019

Saalmann Medical GmbH & Co. KG
% Michael Vent
Official Correspondent
BEO MedConsulting Berlin GmbH
Helmholtzstr. 2
Berlin, DE 10587

Re: K191436
Trade/Device Name: Saalio®
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: EGJ
Dated: September 16, 2019
Received: September 19, 2019

Dear Michael Vent:

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, PhD
Division Director (Acting)
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)*
K191436

Device Name
Saalio®

Indications for Use *(Describe)*
Tap water iontophoresis device intended to treat hyperhidrosis (pathological sweating) affecting hands, feet, and underarms. Any other use or usage beyond this scope is considered un-intended use and may have dangerous consequences.

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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"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."

K191436

510(k) SUMMARY

October 17, 2019

Office of Device Evaluation
U.S. Food & Drug Administration

Dear Madame/Sir;

In accordance with Section 510(k) of the Federal Food & Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of Saalmann® medical GmbH & Co. KG to introduce into interstate commerce for commercial distribution the iontophoresis device Saalio®.

Applicant: Saalmann® medical GmbH & Co. KG
Südbahnstraße 34
32547 Bad Oeynhausen
Germany
Phone: +49 (0)5731 25450 0
Fax +49 (0)5731 25450 11
Email: info@saalmann-medical.de
www.saalmann-medical.de

FDA User Fee Organization Number: 492636

Contact Person: Dr. Rolf Eilers
Phone: +49 (0)5731 25450 0
Email: info@saalmann-medical.de

Device:

a. Proprietary: Saalio®
b. Common Name: Iontophoresis device, Other uses
c. Regulation description: Iontophoresis device
d. Device Class: II
e. Regulation Number: 890.5525
f. Review Panel: Physical Medicine
g. Product Code: EGJ

Predicate Device Information

We claim substantial equivalence for the subject device in intended use, design and function to the predicate device HIDREX PSP1000 manufactured by HIDREX GmbH (K133033).

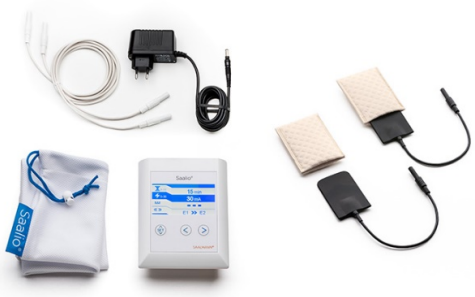
Intended Use / Indication for Use

Tap water iontophoresis device intended to treat hyperhidrosis (pathological sweating) affecting hands, feet, and underarms. Any other use or usage beyond this scope is considered un-intended use and may have dangerous consequences.

Device Description:

The Saalio® unit is a therapeutic device for the treatment of primary focal hyperhidrosis, i.e. excessive sweating of defined body parts. The control device is powered by an external power supply and connected to two electrodes by means of two single cables. The electrodes are brought in contact with the body parts to be treated via a conductive water passage, thus closing the electric circuit. The control device conducts direct current or pulsed direct current (pulsed current) through the body parts.

Depending on the body part to be treated, different electrodes are used. For the treatment of hands and feet, two generous sized silicone electrodes are placed into two trays filled with tap water. The electrodes are covered with foam inserts so as to prevent the body parts to be treated making direct contact with the electrodes. For the treatment of armpits, two smaller silicone electrodes are inserted into sponge pads which have been saturated with tap water. These are then tucked under the armpits for the duration of the treatment. It must be insured that the sponge material is always sufficiently saturated.

The user can adjust the following treatment parameters on the handheld control device: - current setting in mA - duration of treatment in minutes - current type: direct or pulsed current - direction of current - size: 4.7" (W) x 2.5" (H) 5.9" (D)	
Set for hands & feet: - 1 control device - 2 treatment trays - 2 silicone tray electrodes - 2 foam inserts - 2 electrode cables - 1 power supply - 1 operating instructions - 1 textile bag - Tray-size: 11.1” x 15.4” x 2.2”	
Set for armpits: - 1 control device - 1 pair of underarm electrodes with sponge pads - 2 electrode cables - 1 power supply - 1 operating instructions - 1 textile bag	

Performance data:

DC current output	max. 58 V	
	max. 30 mA	
Pulsed current output	max. 58 V	
	max. 30 mA	
	10 kHz	
	1 output mode (pulse-width: 50%)	
Signal type	Monophasic square, at DC: fixed pulsed square signal	Monophasic square, at DC: pulsed square signal
Polarity reversal	manual	
Output regulation	Automatic current regulation	
Timer	Yes	
Display	LCD graphics display with LED backlight	
Self-test	Microprocessor controlled with built-in self-test	

Comparison to legally marketed device HIDREX PSP1000 (K133033) by HIDREX GmbH (Substantial Equivalence):

The Chart below summarizes the similarities and differences.

	SUBJECT DEVICE SAALIO®	**PREDICATE DEVICE Hidrex PSP 1000** (K133033)
Indication for use	Tap water iontophoresis device intended to treat hyperhidrosis (pathological sweating) affecting hands, feet, and underarms. Any other use or usage beyond this scope is considered un-intended use and may have dangerous consequences.	This Tap-Water-Iontophoresis device is intended to treat hyperhidrosis (pathological sweating) affecting hands, feet and underarms. Any other use or usage beyond this scope is considered un-intended use and may have dangerous consequences.
Prescription Use Only	Yes	Yes
Performance		
DC current output	max. 58 V	max. 60 V
	max. 30 mA	max. 35 mA
Pulsed current output	max. 58 V	max. 60 V
	max. 30 mA	max. 35 mA
	10 kHz	9.9 kHz
	1 output mode (pulse-width: 50%)	5 output modes (pulse-width: 50%, 60%, 70%, 80% and 90%)
Signal type	Monophasic square, at DC: fixed pulsed square signal (50%)	Monophasic square, at DC: pulsed square signal
Polarity reversal (to alternate POS and NEG application)	manual	manual
Automatic current regulation	Yes	Yes
Timer	Yes	Yes
Display	LCD graphics display with LED backlight to display all session settings	LCD-multi character display to display all session settings
Microprocessor controlled with built-in self-test	Yes	Yes

Controls		
Meter	digital Monitor	digital Monitor
Intensity	soft sensor buttons	soft sensor buttons
Output Jacks	4 mm insulated connectors	4 / 6mm insulated connectors
Application-accessory		
Feet	treatment tray with silicone/graphite electrode and foam inserts inside	plastic case with metal electrode and towel inside
Hands	treatment tray with silicone/graphite electrode and foam inserts inside	plastic tray / case with metal electrode and towel inside
Axillary applicators	silicone/graphite electrode covered by a sponge pouch	metal electrode covered by a sponge pouch
Dimensions		
Control unit	4.7" (W) x 2.5" (H) 5.9" (D)	7,5" (W) x 2" (H) 5,4" (D)
Hard-shell-case	Non-existent	13.4” x10.8” x 3.3"
Treatment tray	11.1” x 15.4” x 2.2”	10.2” x 15.75” x 2.2”
Axillary sponge cushions	2.6” x 3.7” x 0.5”	2.9” x 3.45” x 1.3”
Foam Insert	9.8” x 13.0”	8.1” x 12.2” (Towel)
Electrodes (feet, hands)	7.9” x 11.4” x 0.1”	4.5” x 11.2” x 2.4”
Electrodes (underarms)	1.9” x 3.0” x 0.1”	1.9” x 2.17” x 0.6”
Power supply		
Type	external	external
Input	100-240 V~ / 50-60 Hz	100-240 V~ / 50-60 Hz
	160-80mA	400mA
Output	24V, max. 300 mA	12V, max. 500mA
	7.2 VA	6 VA
Certification		
CE	YES	YES
GMP/ISO 13485	YES	YES

Difference’s Analysis

These differences were identified:

	Subject device (sd)	**Predicate device (pd)**
1.	Tray electrodes made of silicone/graphite	Tray electrodes made of metal
	The tray electrode of the pd is made of aluminum or stainless steel. Based on experiences metal electrodes tend to corrode due to the galvanic circumstances during the treatment. The metal electrode is bended on the top side upwards and not protected against skin contact, which may lead to skin irritation or burn due to high current and power densities at this site. The tray electrodes of the sd are made of silicone filled with high portion of graphite (typically used for TENS devices). The electrical conductivity is high, the electrode soft and without sharp edges. The inserted graphite is electrically inert. The whole electrode of the sd is completely flat and covered with a foam insert, any skin contact is prevented. Conclusion: The electrodes of the SD are substantially equivalent to the PD ones.	

2.	Flexible underarm electrodes	Stiff/flat underarm electrodes
	The underarm electrode of the pd is also made of metal. Therefore, the electrode is flat and rigid. The surface structure at the underarms differs from patient to patient. In order to compensate these variation, the flat electrode is covered by a relatively thick sponge cushion. A vertically placed sponge cushion tends leak, so that the conducting surface is reduced. This situation might lead to high current and power densities. The underarm electrode of the sd is made of flexible silicone, which easily follows the individual underarm surface topology. This allows the sponge pouch to be flatter, which keeps the whole tap water inside the pouch structure. This result in more stable and controllable current densities and minimizes the risk of high current and power densities. Conclusion: The electrodes of the SD are substantially equivalent to the PD ones.	
3.	Pulsed current: 1 output mode (pulse-width: 50%)	Pulsed current: 5 output modes (pulse-width: 50%, 60%, 70%, 80% and 90%)
	The pd offers 5 different output modes for the pulsed current. The direct current (100% pulse-width) is generally accepted as the most effective type of current. The pulsed current with 50% pulse-width is an accepted alternative. The sd is just offering the direct current and the pulsed current with 50% band-width. For the user there are just two adjustments possible to support the ease of use. Conclusion: The output mode of the SD is substantially equivalent to the PD.	
4.	Soft Bag	Hard shell case
	The pd offers a hard shell case for storing the device and for using the two halves as treatment trays. The hard shell case is too small to allow a parallel treatment of hands and feet at once. Furthermore, storing the wet equipment in the hard shell case supports generating bad smell. The sd comes along with a soft bag, which allows easy evaporation of any remaining moisture. The two trays are ergonomically shaped with an arm cushion and large enough to allow the parallel treatment of hands and feet at once. Conclusion: The soft bag of the SD is substantially equivalent to hard shell case of the PD.	

Non-clinical tests:

To demonstrate substantial equivalence, we performed non-clinical tests according recognized standards:

- Non-clinical tests according to IEC 60601-1 Medical electrical equipment - General requirements for safety were performed in a third party laboratory to demonstrate electrical safety.
- Non-clinical tests according to IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests were performed in a third party laboratory to demonstrate electromagnetic compatibility.
- Non-clinical tests according to IEC 60601-1-11: 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 were performed in a third party laboratory to demonstrate safety in Home Healthcare Environment.

- Non-clinical tests according to ISO 10993-5 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity and ISO 10993-10 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization were performed in a third party laboratory to demonstrate biocompatibility.

Quality Assurance and Manufacturing Controls:

Saalman® medical GmbH & Co. KG operates to an established and certified quality management system.

Conclusion:

The subject device Saalio® is substantially equivalent to the predicate device.