DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2015

Hidrex Gmbh
% Stefanie Bankston
Official Correspondent
2611 Shark Circle
Texas City, TX 77591

Re: K133033
Trade/Device Name: Hidrex PSP1000
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class III
Product Code: EGJ
Dated: February 23, 2015
Received: February 27, 2015

Dear Ms. Bankston,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with

specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S
for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133033

Device Name
HIDREX PSP1000

Indications for Use *(Describe)*
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.

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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Department of Health and Human Services
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."

K133033

510(k) SUMMARY

July 24, 2014

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 HIDREX GmbH to introduce into interstate commerce for commercial distribution the iontophoresis device HIDREX PSP1000.

Applicant:
HIDREX GmbH
Otto-Hahn-Str. 12
D-42579 Heiligenhaus
Phone_: +49 (0)2056 98 11 0
Fax +49 (0)2056 98 11 31
Email: info@hidrex.de

User fee Organization Number: 348050

Contact Person:
Mr. Andreas Kaemper
Phone: +49 (0)2056 98 11 0
Email: kaemper@hidrex.de

US-agent:
Mrs. Stefanie D. Bankston
BEO MedConsulting Berlin GmbH
3001 Ferndale Dr
League City TX 77573
Phone: 713-483 46 17
Email: s.bankston@beoberlin.com

Device:

a. Proprietary: HIDREX PSP1000
b. Common Name: Iontophoresis device, Other uses
c. Regulation description: Iontophoresis device
d. Device Class: III
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 MD-1A (K964208) by R.A. Fischer CO. CORP and to the predicate device Drionic (K831320) by General Medical Company.

Intended Use / Indication for Use:

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.

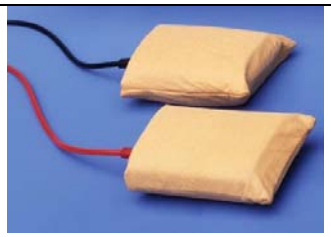
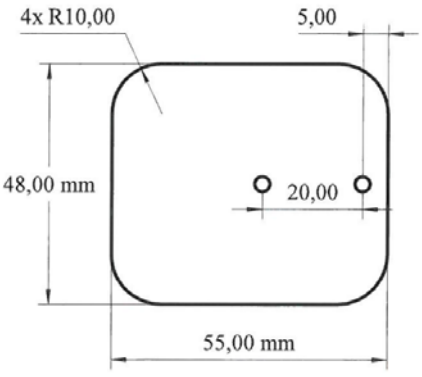
Scientific Concept:

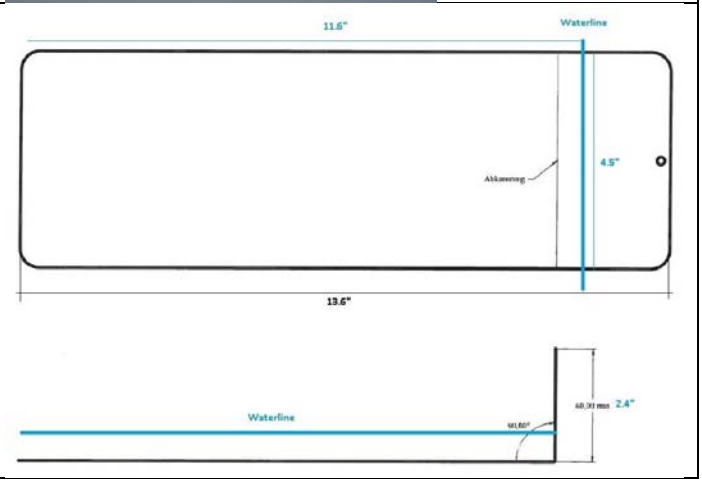
Iontophoresis is a physical process in which ions flow diffusively in a medium driven by an electric field. Iontophoresis is to be distinguished from the carriage of uncharged molecules by diffusive fluxes of other molecules, especially of solvent molecules.
In the treatment of hyperhidrosis, tap water is often the chosen solution for mild and medium forms.
Since 1968, tap water iontophoresis has been employed as the method of choice for treating palmoplantar hyperhidrosis. Special electrodes also allow treatment of axillary hyperhidrosis. Tap water iontophoresis also can extend symptom -free intervals in dyshidrotic palmar eczema. The mechanism action is most likely a functional disturbance of the secretory mechanism of eccrine acini. During the induction phase, treatments are carried out once daily. Current direction may be switched before each treatment or, even better, kept constant until one side, preferably the dominant hand on the anode, is sweating normally. Then polarity is switched until both hands are adequately treated. During the weekly maintenance therapy, current direction is switched before each treatment. The most comfortable means of iontophoretic treatment employs pulsed direct current of high frequency (5-10 kHz) which is better tolerated than continuous direct current. Side effects are minimal and transient. Only slight skin irritation or sensations of discomfort may occur during treatment. Electric burns and shocks can be avoided by following routine precautions. Contraindications for tap water iontophoresis are metallic implants, such as cardiac pacemakers, or orthopaedic joint or bone implants, if they are within the electric circuit.

Device Description:

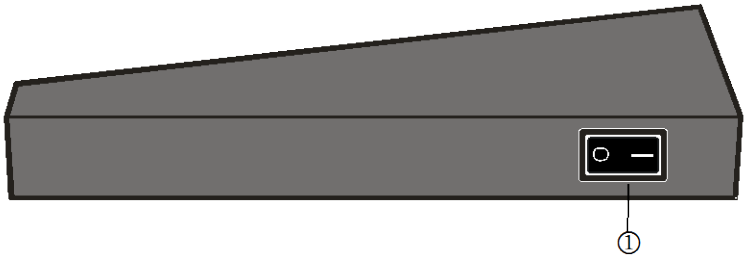
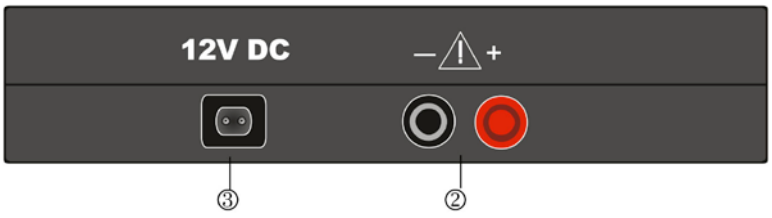
HIDREX iontophoresis devices are primarily intended for treating hyperhidrosis1 (excessive sweating) of hands and/or feet. Provided the optional axillary applicators are utilized, the system can also be used for treating axillary hyperhidrosis.

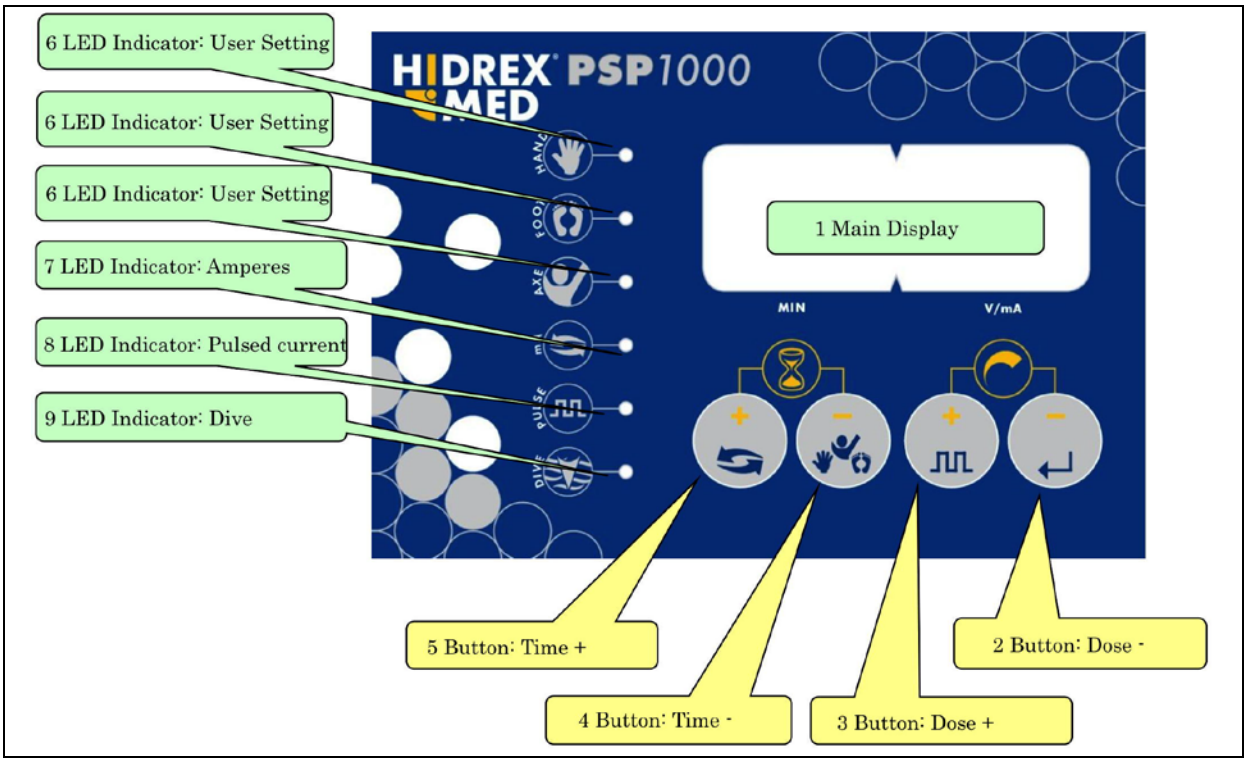
Control unit: The control unit is connected with the power supply/safety wall adapter. The unit includes all connection-jackets to attach the accessories for the treatment. It includes the control-buttons to choose the therapy-mode. Dimension: 190 x 137 x 49 mm	
Power supply / safety wall adapter that is connected with the control unit (secondary plug). The primary plug is connected to the AC-socket in the wall.	

The dual connecting cable set connects the control unit with the therapeutic accessory (patient-applicator). Both, control unit and applicators, have color-coded jackets.	
Hard-shell-case applicator: Accessory for the feet treatment. The electrode is placed inside the hard shell. The user has to put a regular household towel on top of the electrode. Before the start of the treatment the user fills the hard-shell-case with tap-water and covers the electrodes with a towel. Exterior dimensions: 13.4” x 10.8” x 3.3” Interior dimensions: 12.8” x 8.75” x 3”	
Ergonomic treatment tray: Accessory with treatment-electrode for the hand treatment. The electrode is placed inside the tray. The user has to put a regular household towel on top of the electrode. Before the start of the treatment the user fills the trays with tap water and covers the electrodes with a towel. Exterior dimensions: 10.2” x 15.75” x 2.2” Interior dimensions: 6.7” x 12.8” x 2”	
Axillary Sponge Cushions: Accessory with a leather cover for axillary treatment that covers the treatment-electrodes for the armpit treatment. The sponge has to be watered with tap water before the treatment starts. Dimensions: 2.9” x 3.45” x 1.3”	
Axillary Electrodes: Treatment-electrodes for the axillary treatment. Before the start of the treatment the user covers the electrode with an axillary sponge cushion. Dimensions: 1.9” x 2.17” x 0.6”	

Treatment Cover Towel: Applicator for hand and feet treatment. The towel covers the treatment electrodes and has to be watered with tap water before the treatment starts. Dimensions: 8.1” x 12.2”	
Treatment Electrode: Accessory for hand and feet treatment. The electrode is placed inside the hard shell case for feet treatment or inside the ergonomic treatment tray for hand treatment. Before the start of the treatment the user has to cover the electrodes with a towel. Dimensions: 4.5” x 11.2 x 2.4”	

Control unit


1) Therapy system mains ON/OFF switch (mains power switch)

2) Jacks for connecting the dual connecting cable set (treatment electrodes) 3) Connector for the safety wall adapter (12V DC)



1 Display	Main Display to show therapeutic settings
2 Button	Adjustment to lower the dose
3 Button	Adjustment to raise the dose
4 Button	Adjustment to decrease the therapeutic time-span
5 Button	Adjustment to increase the therapeutic time-span
6 LED-Indicator	3 Indicators to show user settings / application mode
7 LED Indicator	1 Indicator to show therapeutic mode activated: current
8 LED Indicator	1 Indicator to show therapeutic mode activated: pulsed current
9 LED Indicator	1 Indicator to show 'ready for treatment' (electric circuit closed)

Current Density of Applicators and Electrodes

Applicator	**Conductive Area [sqin]**	**Max.Density at 30mA [mA/sqin]**	**PeakDensity at 35mA [mA/sqin]**
Hand-Feet, Hard Shell Case individual Water Surface	112.13	0.26	0.31
Hand-Feet, Ergonomic Tray individual Water Surface	90.88	0.33	0.38
Hand-Feet, individual Electrode	122.13	0.24	0.28
Hand-Feet, individual Cover Towel	98.8	0.30	0.35
Axillary, Sponge Cushions	36.75	0.81	0.95
Axillary, individual Electrode	8.25	3.63	4.24

Function:

The HIDREX treatment concept comprises two treatment phases:

Phase 1: The initial phase (therapy initiation) is conducted under a doctor‘s supervision with the doctor´s or the patient´s device. During this stage, patients learn to administer treatments. For therapy initiation, three weekly treatments of approximately 15 minutes each should be scheduled (not more than one treatment per day). Sweat secretion will normalize after approximately 10 treatments.

Phase 2: Long term treatment (maintenance therapy) is necessary because the HIDREX treatment effect is reversible. Patients should conduct maintenance therapy sessions by themselves at home and with their own unit. Depending on the severity of the condition, maintenance therapy involves one to three weekly sessions of approximately 15 minutes each.

The Hidrex PSP1000 with changeable pulse-width allows the innovative adjustment of the pulse-intensity.

Extensive trials showed that the efficiency of pulsed current could be increased dramatically. The effectiveness is not reduced at all compared to direct current when the pulse-width is 90%. The possible pulse-widths are 50%, 60%,70%, 80%, 90% and 100%

Application:

feet

hands

Performance data:

DC current output (automatically regulated)	max. 60 V
	max. 35 mA
Pulsed current output (automatically regulated)	max. 60 V
	max. 35 mA
	9.9 kHz

Comparison to legally marketed device MD-1A (K964208) by R.A. Fischer CO. CORP (Substantial Equivalence):

The Chart below summarizes the similarities and differences:

	DEVICE HIDREX PSP1000	***SE-DEVICE MD-1A (k964208)***
Indication for use	This Tap-Water-Iontophoresis device is intended to treat hyperhidrosis (pathological sweating) affecting hands, feet and underarms.	The MD-1a / MD-2 Galvanic units are indicated for use in the treatment of palmar or plantar hyperhidrosis (abnormal sweating not related to exercise or resulting from another underlying condition) using the technique of tapwater iontophoresis.
Performance		
DC current output	max. 60 V	data not available
	max. 35 mA	0-10 and 0-50 mA
Pulsed current output	max. 60 V	--
	max. 35 mA	--
	9.9 kHz	--
	5 output modes (pulse-width: 50%, 60%, 70%, 80% and 90%)	--
Polarity reversal (to alternate POS and NEG application)	manual	manual
Automatic current regulation	Yes	Only over-current protection
Timer	Yes	--
Display	LCD-multi character display to display all session settings	--
Microprocessor controlled with built-in self-test	Yes	--
Controls		
Meter	digital Monitor	analog meter
Intensity	soft sensor buttons	analog switch/knob
Output Jacks	6mm insulated connectors	6mm insulated connectors
Application-accessory		
Feet	plastic case with towel inside	plastic tray / case with towel inside
Hands	plastic tray / case with towel inside	plastic tray / case with towel inside
Axillary applicators	Pads	--
Dimensions		
Control unit	7,5" (W) x 2" (H) 5,4" (D) Approximately 1 lb	10" (W) x 4" (H) 12" (D) Approximately 5 lb
Hard-shell-case	13.4” x10.8” x 3.3"	data not available
Treatment tray	10.2” x 15.75” x 2.2”	data not available
Axillary sponge cushions	2.9” x 3.45” x 1.3”	data not available
Towel	8.1” x 12.2”	data not available
Electrodes (feet, hands)	4.5” x 11.2” x 2.4”	data not available
Electrodes (underarms)	1.9” x 2.17” x 0.6”	data not available
Conductive area [sqin]		

Hard shell Case	112.13	data not available
Treatment tray	90.88	data not available
Towel	98.8	data not available
Sponge Cushion	36.75	data not available
Electrode (feet, hands)	122.13	data not available
Electrode (underarms)	8.25	data not available
Density at 30mA [mA/sqin]		
Hard shell Case	0.26	data not available
Treatment tray	0.33	data not available
Towel	0.30	data not available
Sponge Cushion	0.81	data not available
Electrode (feet, hands)	0.24	data not available
Electrode (underarms)	3.63	data not available
Stimulating device		
Signal type	Monophasis square, at DC: pulsed square signal, selectable in increments of 10 from 50% to 100%	data not available
Leakage current Type BF	Patient leakage current AC: +000.9 µA Patient leakage current AC SFC: +000.4 µA Patient leakage current DC: +000.0 µA Patient leakage current NAT: +004.2 µA	data not available
Energy output to patient	treatment time: 10 Minutes W = 9,8 V * 0,0008 A * 600 s = 4,704 Ws treatment time: 15 Minutes W = 9,8 V * 0,0008 A * 900 s = 7,056 Ws 1 min => 0,47 Ws = 0,47 J	data not available
Power supply		
	external	internal
Input	100-240 V~ / 50-60 Hz	100-240 V~ / 50-60 Hz
	400mA	data not available
output	12 V=	--
	max. 500mA	--
	6 VA	--
Certification		
CE	YES	NO
Standards	IEC 60601-1:2007	?
GMP	Yes	Yes

Difference's Analysis

These technical differences were identified:

	Subject device (sd)	Predicate device (pd)
1.	DC-current output max. 35mA	DC-current output 0-10 and 0-50mA

	The pd has two output ranges because it uses an analog Ampere-meter. It is very likely to make reading-mistakes using a wide-range-scale while operating in a low-current mode. Therefore, the manufacturer suggests to use the low-range-scale (0-10mA), while using the device in the low-current-mode. However, it is still likely to make mistakes. The sd has a display that shows digital digits. No matter what the current-mode is, it is unlikely to make reading-mistakes. Therefore there is no need to have separated scale-ranges.	
2.	DC and pulsed-current output	Only DC-current output
	A pulse-width of 100% (no pause) is corresponding to the classical DC method. However, pulse-width-method makes the sensation for the user more present because of the physiological 10kHz frequency. The pulsed current output modes are more sensitive. So the risk of skin-irritation is reduced.	
3.	Automatic current regulation and over-current protection	Over-current protection
	The pd, due to its basic concept with analog technology, has a manual current adjustment. The patient/user has to read continuously the analog meter to stay with the appreciated settings. The sd has a microprocessor that is able to watch physical conditions. The sd can automatically adjust the current and keep the therapeutic settings based on the patient's settings. Physical changes caused by the patient, like position or movements, can automatically be compensated.	
4.	Timer	--
	The pd has no timer. The patient has to measure and check the time span for the treatment-session by himself. The sd has a timer that automatically starts the countdown when the treatment starts. The patient's benefit is the automatic ending of the treatment session. The risk for an overdose is reduced.	
5.	Display	Analog meter
	The pd has an analog Ampere-meter. It is very likely to make reading-mistakes using a wide-range-scale while operating in a low-current mode. It is also necessary to have god visibility to be able to read the relatively small numbers on the meter. Reading mistakes are likely. The sd has a display with big digital digits. The display shows the setting as well as the current. The possibility to make reading mistakes is unlikely.	
6.	microprocessor	Analog technology
	The pd operates based on analog technology. The sd operates based on digital technology. The advantage is to be able to check and control the treatment-parameter during the session, to reduce the weight of the device and offer more adjustment for treatment-parameter.	
7.	Digital Monitor	Analog meter
	The pd has an analog Ampere-meter. It is very likely to make reading-mistakes using a wide-range-scale while operating in a low-current mode. It is also necessary to have god visibility to be able to read the relatively small numbers on the meter. Reading mistakes are likely.	

	The sd has a display with big digital digits. The display shows the setting as well as the current. The possibility to make reading mistakes is unlikely.	
8.	Soft sensor buttons	Analog switch/knob
	Analog switches and knobs are subject to corrosion. It is likely that their precision and even functionality is reduced after a few years of use. The sd has foil-insulated micro-switches. They last much longer and it is unlikely that they loose their functionality at all.	
9.	Application accessory axillary-sponge	No axillary-sponge
	Some patients suffer also from axillary hyperhidrosis. To offer effective treatment also for these patients the sd has specialized accessory.	
10.	External power supply	Internal Power supply
	The pd has an internal power supply while the sd has an external power supply. There are no significant differences concerning safety or comfort. A break in the power supply can be fixed more easily with an external one.	

The above mentioned differences between the subject device and the predicate device are due to technological progress. The subject device and its modern technology increase the comfort and benefit for the patient in using the device. Misuse or misunderstanding by using an analog meter is impossible with the clear digital-display of the subject device. All settings are protocolled and displayed in the display. This avoids mistakes in the user-setting. The additional benefit of the pulsed-current is demonstrated in several clinical trials. The safety of the device was demonstrated in non-clinical tests according to recognized standards.

Comparison between materials and principles of use

The HIDREX PSP1000 as well as the predicate device MD-1A GALVANIC UNIT by R.A. Fischer Co. (K964208) use a standard housing made from ABS-Plastic. This housing material is non-toxic and used with many other devices. The same is true for the trays/cases that are used to apply the therapy. None of these materials is in direct contact with the skin for medical purpose. Both devices, the subject device as well as the predicate device, use standard-household-towels that are in direct contact with the patients skin.

The system components are the same. Both systems consist of a central-unit and application components. The subject device has in addition to the foot- and hand-applicator also an axillary applicator. Therefore the subject device offers more benefit to the user than the predicate device.

The principles of use are basically the same. The subject device uses a modern technology like LCD-display to display the setting etc., micro-buttons to adjust and digital controlled processes, while the predicate device has analog technology, like an analog meter to display the current, analog resistor-knob for adjustments and no digital control. Therefore the subject device offers higher comfort and control and advanced usability.

The performance of the subject device and the predicate device are similar concerning the standard dc-current-therapy. The subject device offers a pulsed current in addition, which makes the sensation for the user more present because of the physiological 10kHz frequency.

In conclusion the differences between the subject device and the predicate device don't lead to any harm of the patient or third persons. Comfort and usability is increased with the subject device compared to the predicate device.

Comparison to legally marketed device Drionic (K831320) by General Medical Company (Substantial Equivalence):

The Chart below summarizes the similarities and differences:

	DEVICE HIDREX PSP1000	***SE-DEVICE Drionic (k831320)***
Indication for use	This Tap-Water-Iontophoresis device is intended to treat hyperhidrosis (pathological sweating) affecting hands, feet and underarms.	The Drionic device is indicated for use in the treatment of hyperhidrosis (abnormal sweating) affecting hands, feet and underarms. It uses the technique of tap water iontophoresis.
Performance		
DC current output	max. 60 V	hand or feet treatment: 9V underarm treatment: 18V
	max. 35 mA	hand or feet treatment: 6-14mA underarm treatment: 1-2,5mA
Pulsed current output	max. 60 V	--
	max. 35 mA	--
	9.9 kHz	--
	5 output modes (pulse-width: 50%, 60%, 70%, 80% and 90%)	--
Polarity reversal (to alternate POS and NEG application)	manual	No
Automatic current regulation	Yes	No
Timer	Yes	No
Display	LCD-multi character display to display all session settings	No
Microprocessor controlled with built-in self-test	Yes	No
Controls		
Meter	digital Monitor	No
Intensity	soft sensor buttons	analog control wheel
Output Jacks	6mm insulated connectors	No
Application-accessory		
Feet	plastic tray / case with towel inside	data not available
Hands	plastic tray / case with towel inside	data not available
Axillary applicators	Pads	data not available
Dimensions		
size	Control unit: 7,5" (W) x 2" (H) 5,4" (D)	hand or feet unit: 11,6" (W) x 2,2" (H) 4,9" (D) underarm unit: 4,4" (W) x 0,6" (H) 4,3" (D)
weight	Approximately 1 lb	0,825 lb or 0,374 lb
Hard-shell-case	13.4" x10.8" x 3.3"	data not available

Treatment tray	10.2” x 15.75” x 2.2”	data not available
Axillary sponge cushions	2.9” x 3.45” x 1.3”	data not available
Towel	8.1” x 12.2”	data not available
Electrodes (feet, hands)	4.5” x 11.2” x 2.4”	data not available
Electrodes (underarms)	1.9” x 2.17” x 0.6”	data not available
Conductive area [sqin]		
Hard shell Case	112.13	data not available
Treatment tray	90.88	data not available
Towel	98.8	data not available
Sponge Cushion	36.75	data not available
Electrode (feet, hands)	122.13	data not available
Electrode (underarms)	8.25	data not available
Density at 30mA [mA/sqin]		
Hard shell Case	0.26	data not available
Treatment tray	0.33	data not available
Towel	0.30	data not available
Sponge Cushion	0.81	data not available
Electrode (feet, hands)	0.24	data not available
Electrode (underarms)	3.63	data not available
Stimulating device		
Signal type	Monophasis square, at DC: pulsed square signal, selectable in increments of 10 from 50% to 100%	data not available
Leakage current Type BF	Patient leakage current AC: +000.9 µA Patient leakage current AC SFC: +000.4 µA Patient leakage current DC: +000.0 µA Patient leakage current NAT: +004.2 µA	data not available
Energy output to patient	treatment time: 10 Minutes W = 9,8 V * 0,0008 A * 600 s = 4,704 Ws treatment time: 15 Minutes W = 9,8 V * 0,0008 A * 900 s = 7,056 Ws 1 min => 0,47 Ws = 0,47 J	data not available
Power supply		
	external	internal
Input	100-240 V~ / 50-60 Hz	hand or feet treatment: 9V underarm treatment: 18V
	400mA	data not available
output	12 V=	hand or feet treatment: 9V

		underarm treatment: 18V
	max. 500mA	--
	6 VA	--
Certification		
CE	YES	NO
Standards	IEC 60601-1:2007	No Standards
GMP	Yes	data not available

Comparison between principles of use

The HIDREX PSP1000 has nearly the same system components as the predicate device Drionic by General Medical Company (K831320). Both systems consist of a unit for hand and foot treatment and an application component for underarm treatment.

The principles of use are basically the same. The subject device uses a modern technology like LCD-display to display the setting etc., micro-buttons to adjust and digital controlled processes, while the predicate device has old technology like an analog control wheel to adjust the intensity, a light to display the operating state and no digital control. Therefore the subject device offers higher comfort and control and an advanced usability.

The performance of the subject device and the predicate device are the same concerning the standard dc-current-therapy. In addition the subject device offers a pulsed current which makes the sensation for the user more present because of the physiological 10kHz frequency.

Difference's Analysis

These technical differences were identified:

	Subject device (sd)	**Predicate device (pd)**
1.	DC-current output max. 35mA	DC-current output 6-14mA and 1-2,5mA
	The pd has two output ranges because it has no Ampere-meter. The sd has a display that shows digital digits. No matter what the current-mode is, it is unlikely to make reading-mistakes. Therefore there is no need to have separated scale-ranges.	
2.	DC and pulsed-current output	Only DC-current output
	A pulse-width of 100% (no pause) is corresponding to the classical DC method. However, pulse-width-method makes the sensation for the user more present because of the physiological 10kHz frequency. . The pulsed current output modes are more sensitive. So the risk of skin-irritation is reduced.	
3.	Polarity reversal (to alternate POS and NEG application)	--
	The pd has no possibility to change the polarity. The sd provides a manual adjustable reversible polarity. The user is able to change between positive and negative application.	
4.	Automatic current regulation and over-current protection	No automatic regulation or protection
	The pd has a manual adjustment. The patient/user has to advance the control wheel until there is a comfortable tingle. During the treatment-session the patient/ user is responsible for the intensity by himself without any technical help.	

	The sd has a microprocessor that is able to watch physical conditions. The sd can automatically adjust the current and keep the therapeutic settings based on the patient's settings. Physical changes caused by the patient, like position or movements, can automatically be compensated. This reduces the risk of a harmful high intensity.	
5.	Timer	--
	The pd has no timer. The patient has to measure and check the time span for the treatment-session by himself. The sd has a timer that automatically starts the countdown when the treatment starts. The patient's benefit is the automatic ending of the treatment session. The risk for an overdose is reduced.	
6.	Display	--
	The pd has no display or any other possibility to check setting and current. The sd has a display with big digital digits. The display shows the setting as well as the current. The possibility to make reading mistakes is unlikely.	
7.	Microprocessor	Analog technology
	The pd operates based on analog technology. The sd operates based on digital technology. The advantage is to be able to check and control the treatment-parameter during the session, to reduce the weight of the device and offer more adjustment for treatment-parameter.	
8.	Digital Monitor	--
	The pd has no digital monitor. The sd has a display with big digital digits. The display shows the setting as well as the current. The possibility to make reading mistakes is unlikely.	
9.	Soft sensor buttons	Analog switch/knob
	Analog switches and knobs are subject to corrosion. It is likely that their precision and even functionality is reduced after a few years of use. The sd has foil-insulated micro-switches. They last much longer and it is unlikely that they loose their functionality at all.	
10.	External power supply	Internal Power supply
	The pd has an internal power supply while the sd has an external power supply. There are no significant differences concerning safety or comfort. A break in the power supply can be fixed more easily with an external one.	

The above mentioned differences between the subject device and the predicate device are due to technological progress. The subject device and its modern technology increases the comfort and benefit for the patient in using the device. Because of the automatic current regulation and protection the risk of a harmful high intensity and of an overdose is reduced. All settings are protocolled and displayed in the display. This avoids mistakes in the user-setting. The additional benefit of the pulsed-current is demonstrated in several clinical trials. The attached trial is an explanation as to why the higher levels of voltage and current do not affect safety and effectiveness of the subject device. Furthermore, the safety of the device was demonstrated in non-clinical tests according to recognized standards.

In conclusion the differences between the subject device and the predicate device don't lead to any harm of the patient or third persons. Comfort and usability is increased with the subject device compared to the predicate device.

Non-clinical tests:

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

- To demonstrate electrical safety, software-validation and performance, non-clinical tests were performed according to IEC 60601-1 Medical electrical equipment - General requirements for safety
- To demonstrate safety of the software, non-clinical validation was performed according to IEC 60601-1 Medical electrical equipment - General requirements for safety -- clause 14 Programmable electrical medical systems
- To demonstrate electromagnetic compatibility, non-clinical tests were performed 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.

Quality Assurance and Manufacturing Controls:

HIDREX GmbH operates to an established and certified quality management system according to ISO 13485 requirements.

Conclusion:

The subject device HIDREX PSP1000 is as safe, as effective and performs more comfortable than the predicate devices.