April 1, 2025

Taiwan Medical Electronics Co., Ltd.
Chi-Lin Chen
Regulatory Affairs
Rm. 5, 3F., No. 49, Sec. 3, Zhongshan N. Rd.,
Zhongshan Dist.
Taipei City, 104029
Taiwan

Re: K242041
Trade/Device Name: STOPWET iontophoresis apparatus (SW01)
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: EGJ
Dated: February 26, 2025
Received: February 26, 2025

Dear Chi-Lin Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242041

Device Name

STOPWET iontophoresis apparatus (SW01)

Indications for Use *(Describe)*

STOPWET is a Tap Water Iontophoresis apparatus. Its intended use is to treat hyperhidrosis (excessive sweating) of the hands and feet.

Using this apparatus in any other way than its intended purpose may be dangerous.

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.

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510(k) Summary

Type of 510(k) Submission: Traditional 510(k) Submission

510(k) Submitter: Taiwan Medical Electronics Co., Ltd
Rm. 5, 3F., No. 49, Sec. 3, Zhongshan N. Rd., Zhongshan Dist., Taipei City, Taiwan (R.O.C.)

Contact Person: Chi-Lin Chen
Regulatory Affairs of TME Co., Ltd
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taiwanmedicalelectronics@gmail.com

Preparation Date: 06/30/2024

Device Information:

Common Name:	STOPWET
Model:	SW01
Classification Name:	Iontophoresis device
Regulation:	21 CFR §890.5525
Classification:	Class II
Panel:	Physical Medicine
Product Code:	EGJ

Indications: STOPWET is a Tap Water Iontophoresis apparatus. Its intended use is to treat hyperhidrosis (excessive sweating) of the hands and feet. Using this apparatus in any other way than its intended purpose may be dangerous.

Predicate device: Dermadry (K192749), by Dermadry Laboratories Inc.

Device description: STOPWET is designed for individuals suffering from hyperhidrosis (excessive sweating) of the hands and feet. It includes a pulse current generator and two pairs of containers for performing iontophoresis therapy specifically for hyperhidrosis. Users are required to place their hands or feet inside the containers, which contain dampened absorbent pads, and adjust the amplitude of the pulse current to a comfortable level. The circuit for the pulse current is limited to the distal end of the user's hands or feet, thereby minimizing the risk of cardiac discomfort. Additionally, users have the option to treat either the left or right hand using the single-limb treatment mode or treat both hands simultaneously with the dual-limb treatment mode. STOPWET can be used either in a clinical setting or at home. STOPWET is intended for users aged 13 years and above, including teenagers and adults. For teenagers aged 13 to 21 years, it is recommended to use this apparatus under adult supervision.

Substantial Equivalence Comparison:

Table 1. Substantial Equivalence Comparison between STOPWET and Dermadry (K192749)

Comparison	K242041	K192749	Comparison& Judgement on SE
Trade name	STOPWET	Dermadry	
Intended use	Tap water Iontophoresis apparatus intended to treat hyperhidrosis of the hands and feet.	Tap water Iontophoresis device intended to treat hyperhidrosis of the hands, feet, and underarms.	**[Comparable]** Same for hands and feet, but STOPWET is not applied to underarms.
Indication for use	STOPWET is a Tap Water Iontophoresis apparatus. Its intended use is to treat hyperhidrosis (excessive sweating) of the hands and feet. Using this apparatus in any other way than its intended purpose may be dangerous.	Dermadry is a Tap Water Iontophoresis device. Its intended use is to treat hyperhidrosis (excessive sweating) of the hands, feet and underarms. Using the device in any other way than its intended purpose may be dangerous.	**[Comparable]** Same for hands and feet, but STOPWET is not applied to underarms.
Prescription Use Only	Yes	Yes	**[Same]**
Patient population	For adult and pediatric patients as young as 13 with hyperhidrosis.	For adult patients	**[Difference]** **[D11] Patient population** STOPWET is intended for users aged 13 years and above, including teenagers and adults. For teenagers aged 13 to 21 years, it is recommended to use this apparatus under adult supervision.
Home use	Yes	Yes	**[Same]**
Components	1. Controller (light indicator, current/voltage control, Rotary knob) 2. Electrodes integrated with a container 3. The container for tap water for treatment of feet/hands 4. No electrical current cable/connectors (disposed inside the container) 5. Absorbent pad for feet/hands 6. Not applied to armpits 7. Battery powered	1. Controller (digital monitor user interface, current/voltage control, soft sensor buttons) 2. Electrodes 3. Tray for tap water for treatment of feet/hands 4. Electrical current cable/connectors (4 mm output jack insulated) between controller and electrodes 5. Towel electrode covers for feet/hands 6. Sponges electrode covers	**[Difference]** **[D12] User interface** The UI of STOPWET includes light indicator and Rotary knob. **[D13] Electrode configuration** The electrode pads of STOPWET are integrated with the container. **[D14] Power source** STOPWET is Battery powered.

		for armpits 7. AC-DC Power Supply	
Current profile	Pulse	Pulse	**[Same]**
Waveform	Monophasic square	Monophasic square	**[Same]**
Pulse frequency	10 kHz	10k Hz	**[Same]**
Duty-cycle	90%	90%	**[Same]**
Application area	Hands, foot	Hands, foot, armpits	**[Comparable]** Same for hands and feet, but STOPWET is not applied to underarms.
Current range/ Voltage range/Time	Hands, foot：1-15mA Hands, foot：55 V Hands, foot ： 20 minute (preset duration limited by system)	Hands ： 1~15mA ； Foot ： 1~25mA Hands：48V；Foot：55V Hands, foot ： 20 minute (preset duration limited by system)	**[Difference]** **[D15] Output parameter** ● Maximum current provided by STOPWET is 15 mA. Suggestion for hands is 1~9 mA and for feet is 1~15 mA. ● Maximum voltage provided by STOPWET is 55V for hands and feet.
Current/Voltage control	Automatic control to maintain desired/set Current by automatic adjustment of voltage	Automatic control to maintain desired/set Current by automatic adjustment of voltage	**[Same]**
Maximum power density (Based on area size of electrode pad)	Hands, Feet: 0.0066W/cm^2 (55V)*(15mA)/(12.5cm*10cm)	Feet: 0.00304 W/cm^2 (55V)*(25mA)/(28.2cm*16cm) Hands: 0.00159 W/cm^2 (48V)*(15mA)/(28.2cm*16cm)	[**Difference**] **[D16] Power density** Maximum power density provided by STOPWET is 0.0066 W/cm^2.
Hardware Output Current/ Voltage upper-limits	60 V DC (Software limit: 55V) 30 mA (Software limit: 15 mA)	60 V DC (Software limit: 55V) 30 mA (Software limit: 25 mA)	**[Difference]** **[D15] Output parameter** For STOPWET, maximum hardware output current is limited at 30mA and maximum software output current is limited at 15mA.
Polarity reversal	Automatic polarity reversal Alternating frequency： Hands, feet： Each 5 minute	Automatic polarity reversal Alternating frequency： Hands, feet： Each 5 minute	**[Same]**

Dimensions	1. Controller:14.0cm(L) x14.0cm(W) x 4.5cm(H) 2. Electrodes (feet, hands): 12.5 cm (L) x 10.0 cm(W) 3. Sub-container: 14.0 cm(L) x 14.0 cm(W) x 2.5 cm(H)； 4. Absorbent pad: 13 cm(L) x 13 cm(W)	1. Controller:13.3cm(L) x10.2cm(W) x 3.9cm(H) 2. Electrodes (feet, hands): 28.2 cm (L) x 16.1 cm(W) 3. Treatment tray: 27.5 cm(L) x 8.7 cm(W) x 4.2 cm(H) 4. Towel: 32.1 cm(L) x 21.1 cm(W)	**[Difference]** **[D13] Electrode configuration** The electrodes of STOPWET are integrated with the container.
Power supply	Internal Battery(rechargeable) Input: 5VDC, max 2A, 10VA	External adaptor Input: 100-240VAC/50-60 Hz Output: **5 V DC, max 1.2 A**, 6 VA	**[Difference]** **[D14] Power source** STOPWET is battery powered and the treatment function is disabled during battery charging.

Difference Analysis for STOPWET and Dermadry (K192749)

[D11] Patient population — STOPWET is intended for users aged 13 years and above, including teenagers and adults.

[D12] User interface — The UI of STOPWET includes light indicator and Rotary knob. The output current is adjusted by the rotary knob. The user turns the rotary knob clockwise to activate the controller (accompanied by a clicking sound) and continues turning it clockwise to increase the setup value of the current. The mechanical property of rotary knob has been verified under IEC60601-1, and the operation process related to the UI of STOPWET, such as the marker around the rotary knob as well as the status of indicator light, has been verified under IEC62366.

[D13] Electrode configuration — For the predicate, user should place their left hand in one tray and place their right hand in another tray at the same time. For STOPWET, two electrode pads are integrated with the container and deployed on the same side to avoid the current passing through the user's torso. In addition, the risk of leakage current caused by the controller of STOPWET is negligible under the verification of IEC60601-1.

[D14] Power source — STOPWET is battery powered in order to prevent leaking current from AC power source. In addition, the battery of STOPWET is rechargeable, and the controller stops outputting treatment current when it is charging. This mechanism has been verified under performance test.

[D15] Output parameter — Current upper limit of STOPWET is lower than Dermadry. Considering the maximum power delivered to the user, it is 1485J (0.025A * 90% * 55V * 1200s) for Dermadry, and it is 891J (0.015A * 90% * 55V * 1200s) for STOPWET. This value is lower than Dermadry, however has been proven to be effective.

[D16] Power density — Maximum power density is 0.0066W/cm^2 for STOPWET, and it is higher than the value of Dermadry, because the electrode pads of STOPWET are smaller in order to deploy two electrode pads at one side. In addition, this value is comply with "*Guidance Document for Powered Muscle Stimulator 510(k)s*", which states the

maximum power density should be less than 0.25 W/cm^2.

Performance Testing – Bench:

Electrical safety	Meets the requirement of IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
Electromagnetic compatibility	Meets the requirement of IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
Home Use safety	Meets the requirement of 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.
Usability	Meets the requirement of IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices.
Software development	Meets the requirement of IEC 62304, Medical device software - Software life cycle processes.
Biocompatibility	Meets the requirement of ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.
Battery safety	Meets the requirement of IEC 62133, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
Performance	To demonstrate the output performance of STOPWET as substantially equivalent to the predicate, performance tests were conducted to verify the output parameters claimed by the specification.

Conclusion: After analyzing all testing data and comparing it with the predicated device, it can be concluded that the STOPWET is substantially equivalent to the predicate device.