



February 10, 2020

Dermadry Laboratories Inc.
% Louis-Paul Marin
President
LOK North America Inc.
2025 Michelin Street
Laval, Quebec H7L5B7 Canada

Re: K192749

Trade/Device Name: Dermadry
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: EGJ
Dated: November 8, 2019
Received: November 12, 2019

Dear Louis-Paul Marin:

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

Indications for Use

510(k) Number (if known)

K192749

Device Name

Dermadry

Indications for Use (Describe)

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.

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

1. **Type of Submissions** Traditional
2. **Preparation Date** September 27, 2019 (revised February 9, 2020)
3. **Submitter Address** Dermadry Laboratories inc.
9223 Langelier Blvd
Montreal, Quebec
Canada, H1P 3K9
4. **Contact Person** Louis-Paul Marin, eng, LL.B., LL.M.
President of LOK North America Inc.
Phone: 1 (450) 781-1578 ext. 225
Fax: 1 (450) 681-9663
Email: regulatory@lok-northamerica.com

5. Identification of the Device

Proprietary Name / Trade Name	Dermadry
Regulation	21 CFR 890.5525
Regulation Name	Iontophoresis device
Classification Identification	Device, Iontophoresis, Other Uses
Classification	II
Panel	Physical Medicine
Product Code	EGJ

6. **Identification of the Predicate** Hidrex PSP1000
510(k) Number K133033

7. Indications for Use of the Subject Device

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 unintended use and may have dangerous consequences.

8. Device Description

The Dermadry is a tap water Iontophoresis device intended to treat hyperhidrosis of the hands, feet and underarms. It achieves its action by producing a given low level direct current (DC) level between each of the two applicable members being treated (i.e. the two feet, or the two hands, or the two underarms) for a given amount of time. The current is controlled and transmitted by a controller between two electrodes in separate water basins into which each of the hands or feet are placed, or via two electrodes within water soaked spongy pockets that are placed in each of the underarms. It is for home use by a single patient (single patient). It is for use by prescription under the direction of a physician or clinician, and is intended for adult patients.

9. Substantial Equivalence Determination

	<u>Predicate Device:</u> Hidrex PSP1000	<u>Proposed Device:</u> Dermadry
Intended Use	Tap water Iontophoresis device intended to treat hyperhidrosis of the hands, feet, and underarms.	Same Tap Water Iontophoresis device intended to treat hyperhidrosis of the hands, feet, and underarms.
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. Prescription Use Only	Same 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. Prescription Use Only
Patient Population	Not specified	Difference For adult patients
Home Use	Home Use	Same Home Use
Main Technology	Tap water iontophoresis: Current applied between contralateral treated areas (right/left hands/feet/axillae) via electrodes covered in a towel immersed in tap water into which the members are placed in the case of the hands or feet applications, or alternately via electrodes in sponges wetted with tap water placed within the axillae.	Same Tap water iontophoresis: Current applied between contralateral treated areas (right/left hands/feet/axillae) via electrodes covered in a towel immersed in tap water into which the members are placed in the case of the hands or feet applications, or alternately via electrodes in sponges wetted with tap water placed within the axillae.
Main Equipment	<ul style="list-style-type: none"> - Controller (digital monitor user interface, current/voltage control, soft sensor buttons) - Electrodes - Towel electrode covers for feet/hands - Sponges electrode covers for axillae - Tray for tap water for treatment of feet/hands - Electrical current cable/connectors (6 mm output jack insulated) between controller and electrodes - Power Supply 	Same <ul style="list-style-type: none"> - Controller (digital monitor user interface, current/voltage control, soft sensor buttons) - Electrodes - Towel electrode covers for feet/hands - Sponges electrode covers for axillae - Tray for tap water for treatment of feet/hands - Electrical current cable/connectors (4 mm output jack insulated) between controller and electrodes - Power Supply
Treatment Current/ Voltage/	<ul style="list-style-type: none"> o Hands, Feet, Axilla: up to 60 V max as set by the user, current self-adjusts up 	Differences

Time	<p>to 35 mA to maintain desired voltage, unlimited duration set by user with a labelled recommended duration of approximately 15 min</p> <p>Treatments have user selectable pulse width: 50%, 60%, 70%, 80% and 90% or 100%</p>	<ul style="list-style-type: none"> ○ Hands: 1 to 15mA max as set by the user, voltage self-adjusts up to 48V to maintain desired current, 20 min duration limited by controller ○ Feet: 1 to 25mA max as set by the user, voltage self-adjusts up to 55V to maintain desired current, 20 min duration limited by controller ○ Armpits: 1 to 8mA max as set by the user, voltage self-adjusts up to 30V to maintain desired current, 15 min duration limited by controller <p>All treatments are with a fixed 90% pulse width (not adjustable).</p>
Current/ Voltage control	<p>Automatic Control to maintain set/desired Voltage by automatic adjustment of amperage</p>	<p>Differences Automatic control to maintain desired/set Current by automatic adjustment of voltage</p>
Max Current Density [mA/in²] (per electrode conductive area)	<p>Hands: 0.28 mA/in² Feet: 0.28 mA/in² Armpit: 4.24 mA/in²</p>	<p>Differences Hands: 0.10 mA/in² Feet: 0.17 mA/in² Armpit: 1.06 mA/in²</p>
Hardware Output Current/ Voltage limits	<p>Max: 60 V DC & 35 mA DC (safety circuit limit)</p>	<p>Differences Max: 60 V DC (also lower software limits per treatment as noted above), 30 mA DC (per current limiter, also software limit of 25 mA)</p>
Output Pulsed Current	<p>Monophasic square, pulse-width at 9.9 kHz, user selectable: 50%, 60%, 70%, 80% and 90% or 100%</p>	<p>Differences Monophasic square, pulse-width at 10 kHz: 90%</p>
Polarity reversal	<p>Manual polarity reversal</p>	<p>Differences Automatic polarity reversal every 2.5 min for the armpits or every 5 min for the hands and feet</p>
Dimensions	<p>Control unit: 7.5"(W) x 2"(H) 5.4"(D) Hard-shell-case: 13.4" x 10.8" x 3.3" Treatment tray: 10.2" x 15.8" x 2.2" Axillary sponges: 2.9" x 3.5" x 1.3" Towel 8.1" x 12.2" Electrodes (feet, hands): 4.5" x 11.2" x 2.4" Electrodes (underarms): 1.9" x 2.2" x 0.6"</p>	<p>Differences: Control unit: 4"(W) x 1.5"(H) x 5.2"(D) Hard-shell-case: 3.4" x 10.8" x 3.3" Treatment tray: N/A (same as case) Axillary sponges: 2.6" x 2.5" x 1" Towel: 8.3" x 12.6" Electrodes (feet, hands): 6.3" x 11.1" x 2.1" Electrodes (underarms): 1.8" x 1.67" x 0.3"</p>

Conductive Area (inch²)	Towel (face): 98.8 Sponge Cushion (2 faces+edges): 36.94 Electrode - feet/hands (face+L-edges): 122.13 Electrode - underarms (2 faces): 8.25	Towel (face): 104.1 Sponge Pockets (2 faces+edges): 23.42 Electrode - feet/hands (face+L-edges): 143.43 Electrode - underarms (2 faces+edges): 7.56
Power Supply	AC Adapter: Power Mains supply 100-240V @ 50-60 Hz, Max Power Supply Output: 12 V DC, max 500 mA, 6 VA	Differences AC Adapter: Power Mains supply 100-240V @ 50-60 Hz, Max Power Supply Output: 5 V DC, max 1.2 A, 6 VA

Intended Use and Indication for Use comparisons:

Both systems have the same general intended use and indications for use. Both are also prescription use & home use.

As to the intended patient population, while in the predicate the intended population group is not specified, in the proposed Dermadry an adult population is specified. This should not raise any new questions of safety or effectiveness since this is more specific and restrictive than in the predicate.

The initial phase of device use is conducted under the supervision of the prescribing healthcare professional. This is similar to the predicate device’s first phase of use.

Considering that same intended use, the same indication for use statement, the same home environment of use, and the adult population specificity within that of the predicate, the proposed device is substantially equivalent to the predicate with respect to the intended use and indications.

Technology Comparisons:

The Dermadry implements the same iontophoresis technology as the predicate utilizing the same main components for the treatment of hyperhidrosis of the hands, feet, and armpits.

The differences as highlighted in the table are of an engineering approach nature. Their discussion in terms of equivalence are as follows:

- Differences in the method of controlling the treatment current and treatment current levels:
While in the predicate the treatment current is indirectly controlled via the control of the user set voltage level across the electrodes, in the proposed device the applied current treatment is directly controlled with the system adjusting the voltage across the electrodes to provide the desired current level. As to the treatment current levels, in the predicate, equally for any of the treatment locations, the maximum voltage level that the user can adjust is 60 V, and the current is limited to 35 mA (at any voltage level). In the Dermadry, the directly controlled target current levels have limits depending on treatment location as noted in the table (15, 25, and 8 mA for the hands, feet, and armpits respectively), and the self-adjusting voltages are limited also per the treatment location (48, 55, and 30 V for the hands, feet, and armpits respectively). Therefore, the proposed device treatment current and voltages are in all cases less than the maximums in the predicate with corresponding lower current sensitivity and risk effects. As to effectiveness, although the maximum permissible treatment levels are reduced, the current levels in the Dermadry are of the same order as those typically used in Iontophoresis device for hyperhidrosis (around 10 - 25 mA). Therefore, these differences do not raise any new questions of safety or effectiveness.

- Differences in the treatment durations:

In addition, whereas in the predicate the duration is adjusted and set by the user and is not limited by the controller with only a labelled recommended duration of approximately 15 min for all three treatment areas, in the Dermadry the controller limits the duration of the current administration per the selected treatment area (20, 20, and 15 min for the hands, feet, and armpits respectively). These longer durations in the Dermadry for the hand and feet case are implemented corresponding with its lower possible current levels as compared to the predicate. Similarly as per the above point, this controller’s limited duration should help further minimize possible sensitivity and risks effects given the fixed set limits. Furthermore, the treatment duration limits in the Dermadry are still comparatively safe relative to the lower recommended durations in the hands and feet cases of the predicate given the lower permissible current and voltage levels and the corresponding total possible total energy that the Dermadry can output to the patient. Considering the maximum current and voltages in the worst treatment cases, the maximum energy that can be output to the patient is 1890 Joules over 15 minutes in the predicate as compared to 1650 Joules over 20 minutes for the Dermadry (see table below).

	Max Current (A)	Max Tension (V)	Duration (min)	Max Energy (J)
Predicate Hidrex	0.035	60	15	1890
Dermadry	0.025	55	20	1650

- Differences in the maximum current densities:

Stemming mainly from the lower current levels in the Dermadry, the current density levels are respectively 64%, 39%, and 75% less in the proposed Dermadry for the hands, feet, and underarms electrodes as compared to the predicate levels. These should therefore not present any new risk concerns similarly as noted in the above points while still providing adequately effective current levels.

- Differences in the DC signal pulse width specifications:

Whereas in the predicate the pulse width is user selectable (50% to 100% in increments of 10%), in the Dermadry device it is fixed at 90%. Given that the Dermadry setting is within that of available settings in the predicate and that this characteristic is more related to patient comfort, it does not present any new risk concerns.

- Differences in the polarity reversal specifications:

Whereas in the predicate the polarity is to be reversed manually by the user (approximately when results are initially felt), in the predicate it’s automatically reversed every 5, 5, and 2.5 min for the hands, feet, and armpits respectively. This further ensures that the polarity will be reversed to help minimize pH changes and related effects. Therefore, this does not present any new risk concerns.

- Differences in the hardware output current/voltage limits:

The predicate outer hardware cut-off safety limits is 60 V / 35 mA. This is slightly lower in the Dermadry at 60 V and 30 mA (current limiter circuit). Given the slightly improved safety level, this does not present any new risk concerns.

- Differences in the output jacks:

The jacks in the Dermadry are is of slightly smaller size as compared to the predicate. They are however insulated as in the predicate, and they equally meet the minimum requirements of safety per IEC 60601-1 as in the predicate.

- Differences in the dimensions:

While there are differences in component dimensions, aside from the effect on current density from the electrodes as discussed above, the differences are only dimensional without raising any new questions of safety and effectiveness.

- Differences in the conductive areas:

While there are differences in the conductive areas (lower in the Dermadry underarm electrode and sponge pocket and higher in the feet/hands electrode and towel as compared to the predicate), the lower areas are offset by the lower current levels in the Dermadry with the current densities still be significantly lower than in the predicate without raising new questions of safety or effectiveness as was discussed above under the current density point.

- Differences in the power supply:

While the AC Adapter in the Dermadry has a lower voltage and higher amperage output to the controller than in the predicate, the power output is the same (6 VA) and in both cases the power supply Adapters meet the safety requirements of IEC 60601-1.

Considering the above, the Dermadry proposes the same technology and methods as the predicate to address the same indications. The noted differences in their detail specifications do not present any new questions of safety or effectiveness whereby the two devices are substantially equivalent.

10. Performance Data

- Treatment voltage and amperage accuracy performance testing was performed under simulated conditions.
- Electrical safety and Electromagnetic Compatibility per standards IEC 60601-1 and IEC 60601-1-2.
- Biocompatibility Evaluation per ISO 10993-1 and the related FDA Guidance; Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- Software verification and validation testing per IEC 62304 and FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document, May, 2005.
- Usability performance per IEC 60601-1-6 & IEC 62366-1.
- Home Use safety per IEC 60601-1-11.

As based on the above tests and evaluations, the performance of the Dermadry system do not raise any new safety and effectiveness concerns as compared to the predicate.

11. Conclusion

The Dermadry is substantially equivalent to the currently cleared Hidrex PSP1000 predicate device (510(k) # K133033).