October 11, 2024

Hidroxa Medical AB
Sandra Eriksson Mirkovic, MD
Hidroxa Medical AB
Bjorndammsterrassen 114
Partille, 43342
Sweden

Re: K241267
Trade/Device Name: Hidroxa SE30
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: EGJ
Dated: May 6, 2024
Received: September 17, 2024

Dear Dr. Eriksson Mirkovic:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Rehabilitation 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)*

K241267

Device Name

Hidroxa SE30

Indications for Use *(Describe)*

The intended use of this tap-water iontophoresis device is to treat patients with hyperhidrosis (excessive sweating) of the palms, feet, armpits.

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) #: K241267

510(k) Summary

Prepared on: 2024-09-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hidroxa Medical AB
Applicant Address	Bjorndammsterrassen 114 - Partille N/A 43342 Sweden
Applicant Contact Telephone	+46762611200
Applicant Contact	Dr. Sandra Eriksson Mirkovic
Applicant Contact Email	kundtjanst@hidroxa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hidroxa SE30
Common Name	Iontophoresis device
Classification Name	Device, Iontophoresis, Other Uses
Regulation Number	890.5525
Product Code(s)	EGJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133033	Hidrex PSP1000	EGJ

Device Description Summary

21 CFR 807.92(a)(4)

The medical Hidroxa SE30 is a tap water iontophoresis device. Tap water iontophoresis to treat focal hyperhidrosis is considered state of the art and is one of the first line of treatments in many country's Clinical guidelines.

The Hidroxa SE30 iontophoresis device consists of two electrodes (Aluminium) which are connected to the main unit with one electrode cable each. The electrodes come in two different types. The small electrodes are used to treat hyperhidrosis of the armpits. The electrodes are covered by sponges pockets (cellulose), soaked in tap water and placed directly in the armpits, one in each. One main unit, one AC-adapter and two electrode cables. The large electrodes are used to treat hyperhidrosis of the palms and feet. Tap water is poured into two water bins and one large electrode is placed in each water bin. One towel (cotton) is placed over each of the electrodes to cover them. One hand/foot is then placed on each towel covered electrode. Treatment can then be started. Treatment is performed by the main unit driving an electrical current through the intact skin in the affected treatment areas indirectly through the water in two water bins or via the electrodes in the armpits. Note that the electrodes themselves will never be in direct contact with the skin, but instead cover the sponge pockets/towels during treatment. The main unit is powered from the wall mains using an AC adapter.

The treatment consists of two phases; 1. The initial phase consists of daily to every third day treatments (20 minutes) until desired results are seen. (Ordinary 12 treatments). When the desired results are achieved, switching to the maintenance schedule means treatments (ordinary 20 minutes) 1-3 three times per week to maintain the results.

This treatment can be done at home by the patient themselves or at a clinic with the aid of a medical professional.

The mechanism of action for tap water iontophoresis as a treatment of hyperhidrosis is not fully understood. Several hypotheses have been proposed in different medical papers. One of them is that the ions in the water form a mechanical blockage that prevents sweat from coming out of the sweat glands,
resulting in less sweating. Another theory is that the treatment affects the nerve impulses connected to the sweat glands which leads to

reduced activity in the glands and thus reduced or seized sweat production. Recent studies suggest that iontophoresis increases the threshold value in the nerve cells so that more stimuli is required for an action potential, a signal to the sweat gland, to arise. Iontophoresis is generally considered to be a safe and effective treatment for hyperhidrosis in many cases but not a cure. Regular maintenance treatments are needed to maintain the achieved results.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The intended use of this tap-water iontophoresis device is to treat patients with hyperhidrosis (excessive sweating) of the palms, feet, armpits.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the Hidroxa SE30 is the same as for the predicate device, the Hidrex PSP1000: To treat hyperhidrosis (pathological sweating) affecting hands, feet, and underarms with iontophoresis.

Technological Comparison 21 CFR 807.92(a)(6)

The Hidroxa SE30 and the predicate, the Hidrex PSP1000, share similar operational principles and are intended for the same indication. Key parameters such as treatment method, intended use, and basic functionality are closely aligned between the two devices. Both are designed to deliver controlled electrical currents through water to treat focal hyperhidrosis, and they operate within a similar range of electrical outputs.

Technical differences between the Hidroxa SE30 and the predicate, the Hidrex PSP1000, are minor and do not significantly impact the clinical outcomes or safety profile of the devices. These include minor variations in maximum current output, control options, and user interface elements. The predicate, the Hidrex PSP1000, offers a slightly higher maximum current output and more customizable settings, while the Hidroxa SE30 has features that simplify operation.

The comparison demonstrates that the Hidroxa SE30 is at least as safe and effective as the predicate device, the Hidrex PSP1000, for the intended use of treating focal hyperhidrosis. The minor technical variations do not detract from the equivalence in therapeutic effect and safety profile between the two devices, supporting the conclusion that the Hidroxa SE30 is substantially equivalent to the predicate device, the Hidrex PSP1000.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

These evaluations have been carried out in accordance with the relevant safety and performance standards, ensuring a detailed and methodical review of the device's functionalities and safety.

Usability testing: Extensive usability testing was conducted to ensure the device’s safety and user friendliness.

Firmware testing: The firmware underwent detailed testing to confirm reliable performance, ensuring the software supports the device's operational requirements effectively.

Longevity and shelf life: Endurance testing assessed the device's long-term durability, while shelf life testing confirmed its stability over the intended storage period. The transport and storage protocols were evaluated and validated to be adequate.

Material and biocompatibility testing: The evaluation of materials and their biocompatibility ensured all device components are safe for patient contact.

pH testing: Testing of the pH changes of the water during treatment showed that the pH remained within safe levels during the whole treatment sessions during all test cycles for all test setups.

Batch testing: A plan for batch testing has been established to ensure quality control in the production phase.

External testing at a test house: The device's adherence to international standards was confirmed through testing at an accredited test house, emphasizing the device's compliance with global safety and performance benchmarks.

Through the above discussed testing regimen, covering everything from usability to biocompatibility and batch testing, the Hidroxa SE30 has been evaluated to ensure its safety, efficacy, and reliability. This testing underpins the device's preparedness for clinical use, demonstrating a thorough and committed approach to quality and patient safety.

All requirements have been covered by these tests/verifications and all requirements were deemed fulfilled. The width and depth of these tests/verifications confirm that the Hidroxa SE30 has been subjected to a thorough analysis, in line with necessary specifications

for safety and performance and passed all these tests and evaluations. This testing/evaluation coverage is deemed adequate to validate the device's conformance to the established criteria and therefore its safety, performance and effectiveness.

N/A - no clinical tests submitted, referenced or relied om for this 510k application.

The above mentioned tests/verifications of the Hidroxa SE30 confirm that the Hidroxa SE30 has been subjected to an extensive analysis, in line with necessary specifications for safety and performance and passed all these tests and evaluations. This testing/evaluation coverage is deemed adequate to validate the device's conformance to the established criteria and therefore its safety, performance and effectiveness. It is deemed to be as effective, safe and perform at least as well as the predicate, the HidrexPSP1000 (K133033).