April 7, 2023

Candesant Biomedical, Inc.
Scott Wilson
Head of Regulatory Affairs
3145 Geary Blvd., Suite 711
San Francisco, California 94118

Re: DEN210055
Trade/Device Name: N-SWEAT Patch
Regulation Number: 21 CFR 878.4425
Regulation Name: Skin patch for treatment of hyperhidrosis
Regulatory Class: Class II
Product Code: QVX
Dated: December 2, 2021
Received: December 3, 2021

Dear Scott Wilson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the N-SWEAT Patch, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The N-SWEAT Patch is indicated for treatment of primary axillary hyperhidrosis in adults.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the N-SWEAT Patch, and substantially equivalent devices of this generic type, into Class II under the generic name skin patch for treatment of hyperhidrosis.

FDA identifies this generic type of device as:

> **Skin patch for treatment of hyperhidrosis.** A skin patch for treatment of hyperhidrosis is a prescription topical patch that utilizes a chemical reaction to generate thermal energy in situ for treatment of hyperhidrosis.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 3, 2021, FDA received your De Novo requesting classification of the N-SWEAT Patch. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the N-SWEAT Patch into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the N-SWEAT Patch can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation Labeling
Device failure/malfunction leading to tissue damage	Non-clinical performance testing Shelf-life testing Labeling
Adverse tissue effects as a result of the chemical reaction	Thermal safety testing Clinical performance testing Labeling
Failure to identify correct population and condition	Labeling
Compensatory hyperhidrosis or bromohydrosis	Labeling

In combination with the general controls of the FD&C Act, the skin patch for treatment of hyperhidrosis is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and evaluate:
    (i) Reduction in hyperhidrosis using a validated measure;
    (ii) All adverse events; and
    (iii) Impact of residual chemical on the skin.
(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    (i) Thermal reactivity of the active device component(s);
    (ii) The total energy and energy flux (energy per unit area) of the device that is available to induce heating based on calorimetry; and
    (iii) Characterization of the distribution and homogeneity of the chemical(s) on and within the device.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.
(4) Performance testing must support the shelf life of the device by demonstrating device functionality and package integrity over the labeled shelf life.
(5) Patient and physician labeling must include:
    (i) A summary of the clinical performance testing conducted with the device;
    (ii) A listing of known risks including local adverse events, systemic effects, and adverse changes in perspiration; and
    (iii) Information about the known duration of effect.
(6) Physician labeling must also include:
    (i) Instructions for safe disposal of the device; and
    (ii) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the heating skin patch for treatment of hyperhidrosis they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Shlomit Halachmi at Shlomit.Halachmi@fda.hhs.gov.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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