May 3, 2022

Virility Medical
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: DEN210012
Trade/Device Name: vPatch
Regulation Number: 21 CFR 876.5026
Regulation Name: Non-implanted electrical stimulation device for management of premature ejaculation
Regulatory Class: II
Product Code: QRC
Dated: March 26, 2021
Received: March 30, 2021

Dear Bosmat Friedman:

This letter corrects our previous classification order, dated November 23, 2021, to correct the receipt date of the original De Novo request in the body of the letter.

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 vPatch, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The vPatch is indicated for management of premature ejaculation in males who ejaculate after intromission. It is designed to increase the time between arousal and ejaculation by delivery of short duration, low-intensity electrical stimulation to the perineal muscles and nerves during intercourse.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the vPatch, and substantially equivalent devices of this generic type, into Class II under the generic name non-implanted electrical stimulation device for management of premature ejaculation.

FDA identifies this generic type of device as:

> **Non-implanted electrical stimulation device for management of premature ejaculation.** A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

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 March 30, 2021, FDA received your De Novo requesting classification of the vPatch. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the vPatch 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 vPatch 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:

Identified Risks to Health	**Mitigation Measures**
Use error leading to patient pain, discomfort, or injury	Labeling
Electrical, mechanical or thermal fault, system malfunction, or other device failure resulting in lack of treatment or patient discomfort/injury (e.g., electrical shock, burn, tissue damage, or interference from other medical devices or electrical equipment)	Non-clinical performance testing Electrical safety testing Electromagnetic compatibility testing Software validation, verification, and hazard analysis Shelf-life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling

In combination with the general controls of the FD&C Act, the non-implanted electrical stimulation device for management of premature ejaculation is subject to the following special controls:

(1) The device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(3) 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) Mechanical performance;
(ii) Electrical stimulation parameters; and
(iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:
(i) Specific instructions regarding safe placement and correct use of the device;
(ii) Warning(s) against use by patients with active implanted medical devices; and
(iii) 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 electrical stimulation device for management of premature ejaculation 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 Feba Abraham at 301-796-5772.

Sincerely,

Courtney H. Lias -S

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Office Director
OHT3: Office of GastroRenal, ObGyn,
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