May 1, 2023

Virility Medical, Ltd.
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, NC 28269

Re: K223595
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: April 3, 2023
Received: April 3, 2023

Dear Bosmat Friedman:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223595

Device Name

vPATCH

Indications for Use *(Describe)*

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.

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

[as required by section 807.92(c)]

vPATCH

510(k) Number K223595

5.1. SUBMITTER

Applicant's Name and Address:
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5.2. DEVICE

Trade Name: vPATCH

Classification: **Name:** Non-Implanted Electrical Stimulation Device for Management of Premature Ejaculation
Product Code: QRC
Regulation No: 876.5026
Class: 2
Medical Specialty: Gastroenterology/Urology
Review Panel: GastroRenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)

5.3. PREDICATE DEVICE

vPATCH, manufactured by Virility Medical, Ltd., De-Novo granted DEN210012; Product Code: QRC.
This predicate has not been subject to a design-related recall.

5.4. DEVICE DESCRIPTION

The vPATCH is a single-use disposable patch designed to manage premature ejaculation. It contains electrodes that deliver electrical muscle stimulation (EMS) to the perineal muscles during intercourse to help the user postpone ejaculation. The patch works by delivering short-duration, low-intensity EMS to the perineal muscles and nerves during intercourse. The stimulation contracts the pelvic floor muscles, which consequently delays rhythmic contractions of ejaculation. This increases the time between arousal and ejaculation.

The vPATCH is comprised of several layers which include the cover, electrical circuit board including batteries, and adhesive electrodes. The skin-contacting materials are hydrogel, polyolefin foam, and thermoplastic elastomer (TPE).

The vPATCH is available in two intensity levels (High and Low).

5.5. 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.

** OTC use*

5.6. SUBSTANTIAL EQUIVALENCE

The subject and predicate devices are both single use patches applied to perinium for the management of premature ejaculation.

The following table provides a comparison with the predicate:

Feature	Subject Device vPATCH	Predicate Device vPATCH (DEN210012)	Comparison to Predicate
Reg. Number	876.5026	876.5026	Same
Product Code	QRC	QRC	Same
Indication for Use	*The vPATCH 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.* ** OTC use*	*The vPATCH 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.* ** Rx use*	Same wording of indications for use; The proposed vPATCH has OTC indication vs. Rx indication of the predicate; HF testing including labeling comprehension and self-selection support the expanded indication
Principle of Operation	Patch is applied to the perineum prior to intercourse and switched on to	Patch is applied to the perineum prior to intercourse and switched on	Same

Feature	Subject Device vPATCH	Predicate Device vPATCH (DEN210012)	Comparison to Predicate
	induce stimulation	to induce stimulation	
Biocompatibility	The vPATCH underwent cytotoxicity, sensitization and irritation testing	The vPATCH underwent cytotoxicity, sensitization and irritation testing	Same
Single use	Yes	Yes	Same
Sterility	Not sterile	Not sterile	Same
Packaging Configuration	Available in two package configurations for high and low intensities; each package type contains 4 patches of the same intensity.	Available in three package configurations. The high and low intensity patches are provided in packages that include 4 patches with the same intensity. The new vPATCH starter kit includes one low intensity patch and one high intensity patch to allow the user to decide which intensity is right for him.	A new starter kit was developed to support the OTC indication and allow the user to identify the correct intensity for him.
Stimulation Current	HIGH Intensity: 14.3mA LOW Intensity: 9.9mA	HIGH Intensity: 14.3mA LOW Intensity: 9.9mA	Same
Maximal Stimulation Duration	15 minutes	15 minutes	Same

Any differences in technological characteristics do not raise different questions of safety or effectiveness.

5.7. PERFORMANCE DATA

As a result of some minor device differences, the following pre-clinical tests were repeated/performed:

Biocompatibility:

The following biocompatibility tests were repeated in accordance with FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" (September 2020) and the applicable recognized standards:

- Cytotoxicity
- Sensitization
- Irritation

Non-Clinical Performance Testing:

The following non-clinical performance tests were performed:

- Shelf-Life testing – To demonstrate the packaging integrity and functionality of the

vPATCH is maintained over its claimed shelf-life duration

- Dimensional validation – To demonstrate that critical measurements of the vPATCH are maintained and are consistent during production
- Cover bonding strength – To demonstrate the suitability of the bonding strength of the vPATCH cover
- Liquid ingress protection – To demonstrate the adequate level of protection of the vPATCH against liquid ingress
- Power performance – To demonstrate the satisfactory power performance of the vPATCH device throughout its claimed shelf-life

Usability Testing:

The human factors validation study was combined with a self-selection study and label comprehension study. The combined study was completed using representative users of the vPATCH from three (3) groups (Indicated, Not Indicated, Contraindicated).

The human factors validation study was conducted in a simulated-use format in which intended users performed the tasks that are necessary to use the vPATCH as intended.

Participants had access to the patch itself, the instructions for use (IFU), and any relevant accessories. The results of the study were analyzed to identify root causes of any difficulties or use errors observed during testing. After the validation study concluded, a supplemental study was conducted to gather data to corroborate a minor design change made to further improve usability of the Product.

The vPATCH has been found to be safe and effective for the intended users, uses, and use environments.

5.8. CONCLUSION

The main reason for this submission is to expand the current Rx indication of the vPATCH to an OTC indication. In support of this change, the company has conducted a Human Factors study which included label comprehension and self-selection demonstrating that the intended user population are able to correctly identify themselves as intended users as well as correctly use the device without the need for guidance or intervention of a healthcare professional. With respect to technological differences, the minor modifications implemented to the device have been verified via pre-clinical testing supporting our claim that the vPATCH is as safe and effective as its predicate. The company has provided sufficient pre-clinical and usability testing to demonstrate substantial equivalency to the predicate device. Consequently, it is clear that the vPATCH device is as safe and effective as its predicate and the proposed modifications do not raise any new safety and/or effectiveness concerns.