February 11, 2025

Morari, Inc.
% Hrishikesh Gadagkar
Sr. Princpal
Rqm+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K241897
Trade/Device Name: MOR
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: January 12, 2025
Received: January 13, 2025

Dear Hrishikesh Gadagkar:

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,

Mark R. Kreitz -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241897

Device Name

MOR

Indications for Use *(Describe)*

The MOR System is indicated for the stimulation of healthy perineal muscles and nerves in adult males to improve or enhance sexual performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DATE PREPARED
June 28, 2024

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DEVICE INFORMATION

Proprietary Name/Trade Name:	MOR
Common Name:	Non-Implanted Electrical Stimulation Device for Management of Premature Ejaculation
Classification Name:	Non-Implanted Electrical Stimulation Device for Management of Premature Ejaculation
Regulation Number:	876.5026
Class:	II
Product Code:	QRC
Premarket Review:	DHT3B: Division of Reproductive, Gynecology and Urology Devices. OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Review Panel:	Gastroenterology/Urology

PREDICATE DEVICE IDENTIFICATION
The MOR is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K223595	vPATCH / Virility Medical, Ltd.	✓

The predicate devices have not been subject to a design-related recall.

DEVICE DESCRIPTION

The MOR System is intended for stimulation of healthy perineal muscles and nerves to improve or enhance sexual performance.

The MOR Patch is indicated for the stimulation of healthy perineal muscles and nerves in adult males to improve or enhance sexual performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

The MOR System is a drug-free wearable patch system with single-use electrode patches, a reusable pulse generator, and a smartphone app. Together, these components deliver user-defined electrical stimulation to the perineal region.

Technological Characteristics

The MOR System consists of the following major components:

- Single-Use Patch – Applies the stimulation to skin of the user. Single-use with four electrodes.
- Pulse Generator – Generates the stimulation. Reusable.
- Smartphone App – Used by the user to control the stimulation.
- Charger - Charges the battery in the Pulse Generator.
- Charging Cable – Connects a Charging Power Supply to the Battery Charger
- Cloud Backend – Stores de-identified data collected from the Pulse Generator and Smart Phone App.

1. Pulse Generator Connection
2. Single-Use Patch
3. On/Off Button and LED Indicator Light
4. Pulse Generator
5. Smartphone App (downloadable by the user)
6. Charger
7. Charging Cable
8. Storage Pouch

There are four electrodes on the device that are covered with a medical adhesive and electrically conductive hydrogel that aid in electrode attachment to the perineal area and allow transfer of current to the pelvic floor muscles.

The device is intended to be used by a single user. The device is powered by a single Li-ion battery. The housing includes one push button that allows the user to cycle between stimulation intensity levels and turn stimulation off. The MOR patch and pulse generator are available as individual components and as part of a starter kit. The starter kit includes 1 reusable Pulse Generator, 6 single-use disposable patches, 1 charging station, and 1 travel pouch, along with an IFU and quick reference guide. Each MOR patch

is provided within a sealed foil pouch. The MOR mobile app is available for download on user mobile devices.

INDICATIONS FOR USE

The MOR System is indicated for the stimulation of healthy perineal muscles and nerves in adult males to improve or enhance sexual performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Morari believes that the MOR is substantially equivalent to the predicate devices vPATCH (K223595) based on the information summarized here:

- The subject device has the same intended use as the predicate device cleared in K223595, i.e., a non-implanted electrical stimulation device intended to manage premature ejaculation.
- The subject device and the predicates include a patch that is applied to the perineum before intercourse and switched on to induce stimulation.
- The subject device and predicate (K223595) are non-sterile devices that include a single-use patch, and the device is used for a duration of 15 minutes.

Device Name (Manufacturer)	**MOR System (Morari, Inc.)**	**vPATCH (Virility Medical, Ltd.)**
510k Number		K223595
Regulation Number	876.5026	876.5026
Product Code	QRC	QRC
Indications for Use	*The MOR System is indicated for the stimulation of healthy perineal muscles and nerves in adult males to improve or enhance sexual performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.*	*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.*
Type of Use	OTC	OTC
Principle of Operation	Patch is applied to the perineum prior to intercourse and switched on to induce stimulation.	Patch is applied to the perineum prior to intercourse and switched on to induce stimulation.

Biocompatibility	The MOR patch underwent cytotoxicity, sensitization and irritation testing.	The vPATCH underwent cytotoxicity, sensitization and irritation testing.
Single Use	Yes	Yes
Sterility	Not sterile	Not sterile
Packaging Configuration	Starter kit to include: 1 reusable Pulse Generator, 6 single-use disposable patches, 1 charging station, and 1 travel pouch, along with an IFU and quick reference guide.	Available in two package configurations for high and low intensities; each package type contains 4 patches of the same intensity.
Stimulation Current	10.5mA @140Hz 7.5mA@200Hz	HIGH Intensity: 14.3mA LOW Intensity: 9.9mA
Maximal Stimulation Duration	15 Minutes	15 Minutes

SUMMARY OF NON-CLINICAL TESTING

Hardware physical and functional testing was completed, including basic electrical safety and EMC testing. Software verification and validation testing were performed per IEC 62304:2006+A1:2015, and, therefore, the methods are acceptable. Biocompatibility testing on the MOR patch was performed to demonstrate conformity to ISO 10993-1:2018.

CONCLUSION

Based on the Substantial Equivalence summary provided above, it is evident that MOR (subject device) shares technological characteristics with vPATCH (primary predicate). These devices are designed to be non-implanted electrical stimulation devices to improve or enhance sexual performance by delivery of electrical stimulation to the perineal muscles and nerves.
The minor technological differences identified between the subject device and the primary predicate are apparent in the different electrical stimulation modes. Any differences in technological characteristics do not raise different questions of safety or effectiveness.