April 6, 2026

Virility Medical Ltd.
Natalie Shukrun
Director of QA & RA
24 Ha-Nagar St
Hod HaSharon, Central 4527713
ISRAEL

Re: K252809
Trade/Device Name: in2 Smart (in2S)
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 9, 2026
Received: March 9, 2026

Dear Natalie Shukrun:

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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K252809

Device Name
in2 Smart (in2S)

Indications for Use *(Describe)*
The in2 Smart 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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in2 Smart 510(k) Submission
510(k) Summary

DATE PREPARED: September 01, 2025

510(k) Summary

[as required by section 807.92]

in2 Smart

Submitter:

MANUFACTURER AND 510(k) OWNER:

Virility Medical Ltd.

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PRIMARY CONTACT:

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Phone: +972 52-892-6339

Email: natalie@virilitymedical.com

Device Identification:

Trade Name: in2 Smart (in2S)

Common Name: Non-Implanted Electrical Stimulation Device for Management of Premature Ejaculation

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)

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in2 Smart 510(k) Submission
510(k) Summary

Predicate Device Identification:

The in2 Smart is substantially equivalent to the following primary predicate:

vPATCH, manufactured by Virility Medical Ltd., 510(k) Number: K223595; Product Code: QRC.

This predicate device has not been subject to a design-related recall.

Device Description:

The in2 Smart device is a wearable, hybrid design for the management of premature ejaculation. It includes reusable components for electrical stimulation generation and control, combined with disposable Contact Pads that deliver electrical muscle stimulation (EMS) to the perineal muscles during intercourse to help the user delay ejaculation. The device operates by delivering short-duration, low-intensity EMS to the perineal muscles and nerves, contracting pelvic floor muscles and thereby delaying the rhythmic contractions associated with ejaculation, increasing time between arousal and ejaculation. The stimulation intensity is user-adjustable within a clinically proven safe range. Skin-contacting materials on the disposable Contact Pads include hydrogel and biocompatible electrode layers. Its technological characteristics and principles of operation are substantially equivalent to the predicate device, Virility Medical's vPATCH (K223595), ensuring comparable safety and effectiveness within the intended use.

Indications for Use:

The in2 Smart device 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.

in2 Smart 510(k) Submission
510(k) Summary

Comparison of Technological Characteristics:

Virility Medical believes that the in2 Smart is substantially equivalent to the predicate devices vPATCH (K223595) based on the information summarized here:

- The in2 Smart device has the same intended use and indication as the predicate device cleared under K223595, namely a non-implanted electrical stimulation device for managing premature ejaculation.
- Both the in2 Smart and the predicate device are applied to the perineum prior to intercourse and activated to induce stimulation.
- The in2 Smart and the predicate device operate on the same clinical principles.
- Both the subject device and the predicate (K223595) are non-sterile and include a single-use component.

Substantial Equivalence

The following table provides a comparison with the predicate:

Device Name (Manufacturer) / **Feature**	*Subject Device* **in2 Smart** (Virility Medical, Ltd.)	*Predicate Device* **vPATCH (K223595)** (Virility Medical, Ltd.)
Reg. Number	876.5026	876.5026
Product Code	QRC	QRC
Indication for Use	The in2 Smart 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.	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	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 in2 Smart underwent cytotoxicity, sensitization and irritation testing.	The vPATCH underwent cytotoxicity, sensitization and irritation testing.

VIRILITY MEDICAL

in2 Smart 510(k) Submission
510(k) Summary

Device Name (Manufacturer) / Feature	*Subject Device* **in2 Smart** (Virility Medical, Ltd.)	*Predicate Device* **vPATCH (K223595)** (Virility Medical, Ltd.)
Single use	Contact Pad: Single use	Single use device
Sterility	Not sterile	Not sterile
Packaging Configuration	in2 Smart kit includes 1 multiple use Smart Pod, 1 multiple use Smart Case, 10 single-use disposable Contact Pads and 1 Power Cable, along with an IFU.	Available in two package configurations for high and low intensities; each package type contains 4 patches of the same intensity.
Stimulation Current	Can be personalized by the user, between Low and High intensities: LOW Intensity: 9.9mA±10% HIGH Intensity: 14.3mA±10%	Available in two pre-configured stimulations: LOW Intensity: 9.9mA±10% HIGH Intensity: 14.3mA±10%
Maximal Stimulation Duration	30 minutes	15 minutes

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

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 conducted in accordance with IEC 62304:2006+A1:2015. Usability testing was performed following applicable standards and demonstrated that the device is safe, effective, and user-friendly for its intended users. Biocompatibility testing on the in2 Smart was carried out to demonstrate conformity with ISO 10993-1:2018.

Conclusion

Based on the Substantial Equivalence summary provided above, it is evident that the in2 Smart and the predicate device, vPATCH (K223595), share the same intended use/indications for use and similar technological characteristics and principles of operation. Any differences between the in2 Smart device and its predicate do not present any new issues of safety or effectiveness, as demonstrated by the performance tests, bench tests and usability study conducted on the subject device, and as compared to the predicate.