February 12, 2026

Well-Life Healthcare Ltd.
Jenny Hsieh
President
6F. No.168, Lide St., Jhonghe District
New Taipei City, 23512
TAIWAN

Re: K251760
Trade/Device Name: Well-Life Incontinence Stimulation System (WL-2405i(P))
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: January 9, 2026
Received: January 13, 2026

Dear Jenny Hsieh:

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: The Center for Devices and Radiological Health (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, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

JESSICA K. NGUYEN -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive, Gynecology, and Urology Devices
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Office of Product Evaluation and Quality
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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)*
K251760

Device Name
Well-Life Incontinence Stimulation System (WL-2405i(P))

Indications for Use *(Describe)*
The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) is intended to provide neuromuscular electrical stimulation for the rehabilitation and re-education of weak pelvic floor muscles in adult women. It is indicated for the treatment of stress, urge, and mixed urinary incontinence and to help maintain urinary continence.

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

Type of Submission:	Traditional
Preparation date:	February 11, 2026
510(k) Submitter:	Well-Life Healthcare Ltd.
Address:	6F. No.168, Lide St., Jhonghe District, New Taipei City, 23512, Taiwan
Phone:	+886-2-22266981
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Correspondent Contact:	Jenny Hsieh (Jenny@welllifehealthcare.com.tw)
Device Name:	Well-Life Incontinence Stimulation System (WL-2405i(P))
Common Name:	Nonimplanted electrical continence device
Classification Name:	Stimulator, Electrical, Non-Implantable, For Incontinence
Classification Regulation:	21 CFR 876.5320
Regulatory Class:	II
Product Code:	KPI

1. Indication for Use

The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) is intended to provide neuromuscular electrical stimulation for the rehabilitation and re-education of weak pelvic floor muscles in adult women. It is indicated for the treatment of stress, urge, and mixed urinary incontinence and to help maintain urinary continence.

2. Predicate Device

Manufacture	Device	510(k) Number
Tenscare Ltd.	Perfect PFE	K191312

Note: The predicate device has not been subject to a design-related recall

3. Device Description

The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) is a non-implantable, home use pelvic floor muscle stimulator designed to provide electrical stimulation to the pelvic floor muscles for treatment of stress, urge, and mixed urinary incontinence.

The device contains the electrical stimulator unit, a vaginal probe, a carrying case, 2 lead wires, and a user manual. The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) has four modes. The treatment modes are designed to treat stress, urge, mixed urinary incontinence,

and tone mode by providing targeted stimulation to the pelvic muscles with varying pulse widths, frequencies, ramp-up and ramp-down times, and hold-on and hold-off times. The device is powered by a rechargeable Li-ion battery and controlled by a button interface with adjustable intensity levels. An LCD display shows the current program and intensity level.

The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) includes one reusable (single-patient use), dual electrode vaginal probe electrode (Model: SA-3478) packaged together with the main device.

4. Substantial Equivalence Comparison to Predicate Device

Attribute	Subject Device	Primary Predicate Device:	Comparison
Product Name	The Well-life Incontinence Stimulation System Model: WL-2405i(P)	Perfect PFE	Different
Manufacture	Well-Life Healthcare Ltd.	Tenscare Ltd.	Different
510(K) number	K251760	K191312	Different
Product Code	KPI	KPI	Same
Regulation No.	21 CFR Part 876.5320	21 CFR Part 876.5320	Same
Main function	Pelvic Floor Electrical Stimulation using a Vaginal Probe electrode	Pelvic Floor Electrical Stimulation using a Vaginal Probe electrode	Same

Attribute	Subject Device	Primary Predicate Device:	Comparison
Indication for Use	The Well-Life Incontinence Stimulation System (Model: WL-2405i(P)) is intended to provide neuromuscular electrical stimulation for the rehabilitation and re-education of weak pelvic floor muscles in adult women. It is indicated for the treatment of stress, urge, and mixed urinary incontinence and to help maintain urinary continence.	Perfect PFE is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.	Substantially Equivalent
Intended Papulation	Adult women with stress, urge, or mixed urinary incontinence.	Adult women with stress, urge, or mixed urinary incontinence.	Same
Rx or OTC	OTC	OTC	Same
Use Environment	Home Environment	Home Environment	Same
Number of output modes	4	4	Same
Number of output channels	1	1	Same
Power Sources (s)	3.7V Lithium-Ion Battery	1.5V AA Battery x2	**Different - Note1**
Patient Leakage Current - Normal Condition (μA)	Battery powered (< 10μA)	Battery powered (< 10μA)	Same
Patient Leakage Current Single Fault Condition (μA)	Battery powered (< 50μA)	Battery powered (< 50μA)	Same
Maximum output voltage	40V @500 ohm.	45V @500 ohm.	**Different - Note2 & 3**
Maximum output current	80mA @500 ohm.	90mA @500 ohm.	**Different - Note2 & 3**

Pulse width	Stress: 300μs Tone: 250μs Mixed: 200μs / 300μs Urge: 200μs	Stress: 300μs Tone: 250μs Mixed: 200μs / 300μs Urge: 200μs	Same
Frequency	Stress: 50Hz Tone: 35Hz Mixed: 10Hz/50 Hz Urge: 10Hz	Stress: 50Hz Tone: 35Hz Mixed: 10Hz/50 Hz Urge: 10Hz	Same
Level (Intensity Setting Index)	0-80 (mA)	0-90 (mA)	**Different - Note2**
Timer	Default Stress: 20 min Tone: 20 min Mixed: 20 min Urge: 20 min Default 20 min Adjustable 5-20 min	Default Stress: 20 min Tone: 20 min Mixed: 20 min Urge: continuous Adjustable 0-90 min	**Different - Note3**
Waveform	Asymmetrical, biphasic rectangular pulse	Asymmetrical, biphasic rectangular pulse	Same
Maximum Phase Charge	23.76 μC	24.29 μC	**Different – Note 3**
Maximum average power density	0.166 mW/cm²	0.0116 mW/cm²	**Different – Note 3**
Software/Firmware/MCU	YES	YES	Same
Automatic no-load trip	YES	YES	Same
Accessories	Include 1 Vaginal Probe Electrode With electrode Area 4.24cm^2	Include 1 Vaginal Probe Electrode With electrode Area 4.25cm^2	Same

Note 1

The Subject Device is powered by a rechargeable lithium battery, whereas the Primary Predicate Device uses two AA batteries. This represents a difference in power supply design but does not affect the functional performance of the device.
The Subject Device has undergone testing in accordance with IEC 60601-1, which confirms the electrical safety and compatibility of the lithium battery configuration.

Note 2

The output voltage of the Subject Device is 40Vwith 0-80 levels, while the Primary Predicate Device is rated at 45V with 0-90 levels. Although this represents a slight variation, both values fall well within the acceptable safety limits established by the IEC 60601-2-10 standard for electrical stimulators.

The sponsor conducted appropriate bench testing to support that despite the slight differences in some parameters of the device, the electrical stimulation provided by the subject device is substantially equivalent to the predicate device.

Therefore, despite the voltage difference, the Subject Device and Primary Predicate Device demonstrate equivalent safety and effectiveness.

Note 3

The Subject Device includes four preset programs, each with a default treatment duration of 20 minutes, identical to the Primary Predicate Device (Perfect PFE, K191312). The electrical stimulation parameters of the subject device are substantially equivalent to the electrical stimulation parameters of the predicate device.
Each time the device is powered on, and a mode is selected, the timer automatically resets to its default 20-minute setting. The treatment duration can be adjusted downward from 5 to 20 minutes but cannot exceed 20 minutes.

5. Non-Clinical Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and FDA Guidance "Use of International Standard ISO 10993-1" (2016).
- Electrical Safety testing according to IEC 60601-1: 2005+A1:2012+A2:2020 - Medical electrical equipment – Basic safety and essential performance
- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2014+AMD1:2020 - General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- Software Verification and Validation Testing according to FDA's Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- Performance testing according to IEC 60601-1-11, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- Performance test according to IEC 60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- Electrical performance testing to verify the stimulation parameters

All pre-determined acceptance criteria were met.

6. Conclusion

The subject device and the predicate device have the same intended use/indications for use and similar technological characteristics. The differences between the subject device and the predicate device do not affect the principles of operation, underlying technology, electrical stimulation parameters and principal functionality. The differences between the subject device and the predicate device do not present different questions of safety or effectiveness and the performance tests conducted on the subject device support the device is as safe and effective as the predicate.

Therefore, the subject device is substantially equivalent to the predicate device.