December 29, 2022

Well-Life Healthcare Limited
Jenny Hsieh
Official Correspondent
6F., No. 168. de St., Jhonghe District
New Taipei City, 235
Taiwan

Re: K222528
Trade/Device Name: Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HIR
Dated: November 17, 2022
Received: November 30, 2022

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 (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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222528

Device Name
Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)

Indications for Use *(Describe)*
Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA) include
Vaginal Probe SA-2876, SA-25145, SA-20100, SA-3478, SA-2687 & Rectal Probe SA-1483, SA-19108, SA-1563, SA-2486 are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of week pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

Type of Use *(Select one or both,* as *applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) X 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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510(k) Summary

1. Type of Submission: Traditional
2. Preparation date: 12/28/2022
3. Submitter: Well-Life Healthcare Ltd.

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Contact: Jenny Hsieh
(Jenny@welllifehealthcare.com.tw)

Registration number: 3006850006

4. Identification of the device:

510(K) No	K222528
Device Name:	Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)
Common or usual name:	Incontinence Stimulation/EMG Electrode Probe
Model:	Vaginal Probe: SA-2876, SA-25145, SA- 20100, SA- 3478, SA-2687 Rectal Probe: SA-1483, SA-19108, SA-1563, SA- 2486
Classification name:	Nonimplanted Electrical Continence Device
Classification Panel:	Gastroenterology-Urology
Device Classification:	II
Regulation Number:	21 CFR Part 876.5320
Product Code	KPI & HIR

5. Identification of the Predicate and Reference Devices:

Predicate Device:	
510(K) No	K122194
Predicate Device Name:	LIFE-CARE VAGINAL PROBE, LIFE-CARE ANAL PROBE. The predicate has not been subject to a design-related recall.
Model:	Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03/A, PR-04/04A, PR-10A, PR-11A, PR-14A, for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe.

Classification name:	Nonimplanted Electrical Continence Device
Classification Panel:	Gastroenterology-Urology
Device Classification:	II
Regulation Number:	21 CFR Part 876.5320
Product Code	KPI & HIR

Reference Device:	
510(K) No	K191312
Reference Device Name:	TensCare Ltd. Perfect PFE
Model:	Vaginal Probe: Liberty Loop Vaginal Probe (X-VPL) Electrical Stimulator: Perfect PFE
Classification name:	Nonimplanted Electrical Continence Device
Classification Panel:	Gastroenterology-Urology
Device Classification:	II
Regulation Number:	21 CFR Part 876.5320
Product Code	KPI

6. Intended Use and Indications for use of the Subject Device:

Intended Use

Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. Electromyographic (EMG) sensing of the pelvic floor muscles.

Indications for use

Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA) include Vaginal Probe SA-2876, SA-25145, SA-20100, SA-3478, SA-2687 & Rectal Probe SA-1483, SA-19108, SA-1563, SA-2486 are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of week pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

7. Description of the Device:

Well-Life Probe Electrodes for Stimulation/EMG Probes (Model: SA) contains two types of products, Vaginal Probe and Rectal Probe. The Well-Life Probe Electrode for Stimulation/EMG Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of week pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

Well-Life Probe Electrode for Stimulation/EMG (Vaginal Probe) SA-2876, SA-25145, SA-20100, SA-3478, SA-2687 are lightweight cylinders consisting of two or three independent conductive rings or plates that are paired and isolated, physically, and electrically. The cylinder is shaped with a waist and handle for positioning in the vaginal canal for incontinence treatment and easy removal after treatment. It is watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use by a single user in home or clinic up to 300 times, 15 minutes per session equal to 10 months of daily operation. It does not require sterilization, but does require washing before and after reuse according to the cleaning method as recommended in the user manual.

Well-Life Probe Electrode for Stimulation/EMG (Rectal Probe) SA-1483, SA-19108, SA-1563, SA-2486 are lightweight cylinders consisting of two or three independent conductive rings that are paired and isolated, physically, and electrically. The cylinder is shaped with a waist and handle for positioning in the rectal canal for incontinence treatment and easy removal after treatment. It is watertight to allow for washing with soap and water before and after uses. The electrode is designed for repeated intermittent use by a single user in home or clinic up to 300 times, 15 minutes per session equal to 10 months of daily operation. It does not require sterilization, but does require washing before and after reuse according to the cleaning method in user manual. The probe is constructed of stainless steel, acrylonitrile butadiene styrene (ABS), and polyvinyl chloride (PVC).

8. Comparison of Technological Characteristics

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Remark
510K number	K222528	K122194	K191312	-------
Device Name	Well-Life Probe Electrode for Stimulation/EMG Probe Model: SA Vaginal Probe: SA-2876, SA-25145, SA-20100, SA-3478, SA-2687 Rectal Probe (Rectal Probe): SA-1483, SA-19108, SA-1563, SA-2486	LIFE-CARE VAGINAL PROBE LIFE-CARE ANAL PROBE Vaginal Probe: PR-02/ PR-02A, PR-03/ PR-03A, PR-04/ PR-04A, PR-10A, PR-11A, PR-14A Anal Probe: PR-06/06A, PR-12A, PR-13/13A	TensCare Ltd. Perfect PFE Vaginal Probe: Liberty Loop Vaginal Probe (X-VPL) Electrical Stimulator: Perfect PFE	-------
Product Code	KPI & HIR	KPI & HIR	KPI	Same as Predicate
Prescriptive or Over-the-Counter (OTC)	OTC and RX	RX	OTC and RX	Instructions are equivalent to K191212 and include information for suitable stimulator selection
Regulation No	21 CFR Part 876.5320	21 CFR Part 876.5320	21 CFR Part 876.5320	Same as Predicate
Indications for Use	Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA) include Vaginal Probe SA-2876, SA-25145, SA-20100, SA-3478, SA-2687 & Rectal Probe SA-1483, SA-19108, SA-1563, SA-2486 are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of week pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.	The everyway incontinence stimulation electrode, model pr-02/02a, pr-03/03a, pr-04/04a, pr-10a, pr-11a, pr-14a for life-care vaginal probe & pr-06/06a, pr-12a, pr-13/13a for life-care anal probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.	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.	Same as Predicate

Intended Use	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles.	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles.	Perfect PFE is intended to provide electrical stimulation and neuromuscular reeducation 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.	Same as Predicate
Contact Duration	Intermittent mucosal contact<30 min/ session-Stim<1 hour/session-EMG not exceeding 1hr combined	Intermittent mucosal contact<30 min/ session-Stim<1 hour/session-EMG not exceeding 1hr combined	Unknown	Same as Predicate
Product Type	Probe only	Probe only	Probe + Electrical Stimulator	Same as Predicate
Electrode Placement	Vaginal Rectal (Anal)	Vaginal Anal	Vaginal	Same as Predicate
Usage Conditions	Reusable-Single Patient	Reusable-Single Patient	Reusable-Single Patient	Same
Electrode Material	Stainless steel	Stainless steel	Stainless Steel	Same
Frequency (Hz)	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 50Hz	No energy transmission	Max: 50Hz	Equivalent to Predicate
Pulse Width	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 300 us	No energy transmission	Max: 300us	Equivalent to Predicate
Maximum Output Voltage (V)	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 45V 500Ω	No energy transmission	45V @500Ω	Equivalent to Predicate

Maximum Output Current (A)	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 90mA @500Ω	No energy transmission	90mA @500Ω	Equivalent to Predicate
Max R.M.S Power Density (W-r.m.s/cm^2)	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 0.25 W/cm^2 @500Ω	No energy transmission	0.014 W /cm2 @500Ω	Equivalent to Predicate
Max R.M.S Current Density (mA-r.m.s/cm^2)	No energy transmission However, the specifications of the matched Electrical stimulator must be smaller than 2 mA /cm2 @500Ω	No energy transmission	0.318 mA/cm2 @500Ω	Equivalent to Predicate
Electrode Area (Single-Electrode)	Vaginal SA-2876: 7.62 cm^2 SA-25145: 7.87 cm^2 SA-20100: 6.25 cm^2 SA-3478: 4.25 cm^2 SA-2687: 6.12 cm^2 Rectal SA-1483: 1.93 cm^2 SA-19108: 3.77 cm^2 SA-1563: 2.17 cm^2 SA-2486 2.85 cm^2	Vaginal PR-02A: 7.65 cm^2 PR-03A: 7.87 cm^2 PR-04A: 6.25 cm^2 PR-10A: 6.25 cm^2 PR-11A: 6.25 cm^2 PR-14A: 6.00 cm^2 Anal PR-06A: 1.93 cm^2 PR-12A: 2.26 cm^2 PR-13A: 3.77 cm^2	Liberty Loop Vaginal Probe (X-VPL): 4.24cm^2	Similar/Equivalent

9. Statement of conformity

List of FDA-recognized voluntary consensus standards cited in this submission.

Recognition Number	Standard Designation Number and Date	Title Of Standard	Date Of Recognition
2-258	ISO 10993-1 Fifth Edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	01/14/2019
2-245	ISO 10993-5 Third Edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	02/23/2016
2-296	ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	05/30/2022
2-291	ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices — Part 23: Tests for irritation	06/07/2021
17-14	ANSI AAMI NS4:2013(R)2017	Transcutaneous Electrical Nerve Stimulators 2013(R)2017	01/14/2019
14-497	ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	12/23/2016
5-114	IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices	12/23/2016
19-4	IEC 60601-1:2005, MOD	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance	07/09/2014
3-129	ANSI AAMI EC53:2013/(R)2020	ECG trunk cables and patient leadwires	06/07/2021

10. Non-Clinical Testing Summary:
Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

1) Biocompatibility Patient contacting components are in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5 Third Edition 2009-06-01), sensitization (ISO 10993-10 Fourth edition 2021-11), irritation (ISO 10993-10 Fourth edition 2021-11) and Sample preparation and reference materials (ISO 10993-12 Fourth Edition 2012-07-01).

2) Recommendations and requirements outlined in the FDA guidance "Design Considerations for Devices Intended for Home Use," 21 CFR Part 801, and 21 CFR Part 809.10 were followed. A comparison to the instructions of the reference device which have been validated for OTC use were conducted to support OTC instructions in the labeling. Based on the similarity of the Well-Life Probe Electrode to the predicate and reference devices with respect to design, indications for use, cleaning instructions, and labeling materials, additional usability testing was determined not to be necessary.

3) Recommendations and requirements outlined in the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" were followed for reprocessing and cleaning instructions in the labeling.

4) Performance Bench Testing was performed to verify the performance to specifications of the proposed device and included the following:

- Performance Bench testing was performed to verify the performance to specifications with ANSI AAMI NS4:2013(R)2017.

- ASTM F1980-16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices" was followed for accelerated aging of the subject device. After accelerated aging, functional performance testing was conducted on aged samples to support the proposed shelf life of 2 years.

- Testing was performed to verify the performance to specifications of the proposed device to subclause 8.5.2.3, *Patient Leads of Patient Cables* of IEC 60601-1:2005, MOD to comply with 21 CFR 898. Electromagnetic Compatibility (EMC) and Electrical Safety Testing beyond subclause 8.5.2.3, Patient Leads of Patient Cables of IEC 60601-1:2005, MOD was not determined to be necessary because the subject device is an individual component of an electrical system that does not generate or control electrical power, similar to the predicate device.

- Performance Testing Bench- Tensile strength of cable connection test per ANSI AAMI EC53:2013/(R)2020 related test methods for lead wire strength of cable connection test to ensure the safety of related electrical connection of products.

11. Conclusion:

After comparison and evaluation, the subject device "Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)" has many of the features and technological characteristics of the predicate device, and performance testing supports that any differences do not impact safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.