September 17, 2021

Shenzhen Med-link Electronics Tech Co, Ltd
Yongfen Yang
Regulatory Affairs Specialist
4th And 5th Floor, Building Two, Hualian Industrial Zone,
Xinshi Community Dalang Street
Shenzhen, Guangdong 518109
China

Re: K210441
Trade/Device Name: Incontinence Probe
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HIR
Dated: August 10, 2021
Received: August 13, 2021

Dear Yongfen Yang:

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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210441

Device Name
Incontinence Probe

Indications for Use *(Describe)*
The Incontinence Probes 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.

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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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

Name and Address:	Shenzhen Med-link Electronics Tech Co., Ltd. 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, Shenzhen, Guangdong 518109 . People's Republic of China
Primary Contact:	Yongfen Yang (Regulatory Affairs Specialist) E-mail: mdl012@medlinket.com Tel: 0086-755-61568825 Fax: 0086-755-61120055
Data of Preparation:	September 15, 2021

2. Device Information:

Trade Name:	Incontinence Probe
Common Name:	Incontinence Probe
Classification Number:	21 CFR 876.5320
Classification Name:	Nonimplanted Electrical Continence Device
Product Code:	KPI, HIR
Regulatory Class:	II
Review Panel:	Gastroenterology/Urology

3. Identification of the Predicate Device:

Device Name	Common Name	Manufacture	510(k)
Fuji Dynamics Incontinence Stimulation Electrode	Incontinence Probe	Fuji Dynamics Ltd.	K161055

4. Device Description:

The Incontinence Probe models PE0001, PE0002, PE0003, PE0004, PE0005, PE0006, PE0007 ,PE0008, PE0009, and PE0010 are stand-alone probes/electrodes, which can be placed inside the adult rectum or female vagina to transmit electrical stimulation signals or pelvic floor EMG signals when connected to pelvic electrical stimulators or EMG biofeedback devices during the treatment of urinary incontinence . All the models are reusable for a single patient except PE0003, which is a disposable vaginal probe. The probes are not packaged with specific pelvic floor muscle stimulators and EMG/biofeedback equipment but are compatible with low-frequency (less than 1000Hz working frequency) stimulators or EMG/biofeedback devices that meet the standards of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10 and use 2.0 DIN connection. The probes are made of S304 stainless steel and Acrylonitrile-Butadiene-Styrene (ABS). The probes are designed for use in home or clinic by a single user. The probes do not require sterilization but need cleaning for reuse according to the cleaning instructions provided in the instructions for use manual.

5. Indication for Use:

The Incontinence Probes 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.

6. Comparison of the Technological Characteristics with Predicate Device:

Characteristic	**Vaginal Probe**		**Rectal Probe**	
	Predicate device	Subject device	Predicate device	Subject device
510(K) Submitter	Fuji Dynamics Ltd.	Shenzhen Med-link Electronics Tech Co. Ltd.	Fuji Dynamics Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.
Model	Fuji Dynamics Fuji-01/ 02 / 03/ 04 / 05/ 06/ 07/ 14/ 15	PE0002,PE0003,PE0005,PE0007,PE0009, PE0010	Fuji Dynamics Fuji- 08/ 09/ 10/ 11/ 12 / 13/ 14/ 15	PE0001,PE0004, PE0006,PE0008
Number of Electrode	2–Stimulation / EMG	Same	2–Stimulation / EMG	Same

Usage Conditions	Reusable – single patient	Except the model PE0003 which is disposable, the other models are reusable-single use	Reusable – single patient	Same
Electrode Material	Stainless Steel & ABS	Same	Stainless Steel & ABS	Same
Electrode Placement	Vagina	Same	Rectum	Same
Contact Duration	Intermittent mucosal contact < 30 min/session –Stim < 1 hour/session – EMG not exceeding hr combined Stim/EMG	Same	Intermittent mucosal contact < 30 min/session –Stim < 1 hour/session – EMG not exceeding hr combined Stim/EMG	Same
Sterility	Non-sterile	Same	Non-sterile	Same

In addition to the differences noted in the above table, there are differences in dimensions between the subject and the predicate device. However, these differences do not raise new questions of safety or effectiveness and the testing mentioned below showed that the subject is substantially equivalent with the predicate.

7. Non-clinical Testing:

The sponsor provided the following performance testing to support substantial equivalence:

- Biocompatibility per ISO 10993 – Cytotoxicity, Sensitization, Vaginal irritation, and Rectal irritation
- Shelf-life validation –functional testing
- Electrical Safety testing per IEC 60601-1
- Performance Bench Testing
    - On the probes - visual testing, electrical output verification testing after connecting the probe with a compatible host, cable dielectric strength testing, and lead wire plug to instrument connector contact resistance testing
    - On the lead wires per ANSI/AAMI EC53

The protocol and results of the provided non-clinical testing are acceptable.

8. Conclusion:

Based on the comparison and analysis in this submission, it can be concluded that Incontinence Probe is substantially equivalent to the predicate device.