



Food and Drug Administration
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July 12, 2016

Fuji Dynamics Ltd.
Kam Tim Ng
Engineer
1-3, 23/F., Laws Commercial Plaza, 788 Cheung Sha Wan Road
Hong Kong
China

Re: K161055
Trade/Device Name: Fuji Dynamics Incontinence Stimulation Electrode, Models:
Fuji – 01/ 02/ 03/ 04/ 05/ 06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/ 15
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Codes: KPI, HIR
Dated: April 5, 2016
Received: April 14, 2016

Dear Kam Tim Ng:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161055

Device Name

Fuji Dynamics Incontinence Stimulation Electrode

Models : Fuji - 01/ 02/ 03/ 04/ 05/ 06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/ 15

Indications for Use (Describe)

The Fuji Dynamics Incontinence Stimulation Electrodes 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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E. 510 (k) Summary (per 21 CFR 807.92)

510 (k) Summary

Date of submission prepared : 5 April 2016

The assigned 510(k) number is : K161055

1. Submitter's Information

Submitter: Fuji Dynamics Ltd.
Unit 2301-03, Laws Commercial Plaza
788 Cheung Sha Wan Road, Kowloon
Hong Kong

Contact Person: Kam Tim Ng

Tel: (852) 2786 4218

Fax: (852) 2744 6775

2. General Device Information

Name of Device : Fuji Dynamics Incontinence Stimulation Electrode
Models:
Fuji-01 / 02/ 03/ 04/ 05/ 06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/ 15

Classification Name : Stimulator, Electrical, Non-implantable, For Incontinence ,
Perineometer & EMG Biofeedback System

Product Code : KPI, HIR

Regulatory Class : Class II

3. Predicate Device Information

Hollister Vaginal Stimulation/EMG Probe-Tampon (K971541) and Anal Stimulation
/EMG Probe-w/Stop (K990456)

4. Device Description

The Fuji Dynamics Incontinence Stimulation Electrode models Fuji-01/ 02/ 03/ 04/ 05/
06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/ 15 are the light weight cylinder 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 comfort positioning in
vaginal canal for incontinent treatment and easy in removing after treatment. It is

E. 510 (k) Summary (per 21 CFR 807.92)

watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use in home or clinic for up to one year by a single user. It does not require sterilization, but does required washing and drying between uses.

5. Intended use

The Fuji Dynamics Incontinence Stimulation Electrode, model Fuji-01/ 02/ 03/ 04 / 05/ 06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/ 15 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.

E. 510 (k) Summary (per 21 CFR 807.92)

6. Comparison to the Predicate Device

The following features are identical among the predicate device and our models.

Characteristic	Vaginal Probe		Anal Probe	
	Predicate device	Subject device	Predicate device	Subject device
Model	Hollister K971541 Vaginal Stimulation/ EMG Probe-Tampon	Fuji Dynamics Fuji-01/ 02 / 03/ 04 / 05/ 06/ 07/ 14/ 15	Hollister K990456 Anal Stimulation/ EMG Probe-w/Stop	Fuji Dynamics Fuji- 08/ 09/ 10/ 11/ 12 / 13/ 14/ 15
Number of Electrode	2–Stimulation / EMG	Same	2-Stimulation / EMG	Same
Usage Conditions	Reusable – single patient	Same	Reusable – single patient	Same
Electrode Material	Stainless steel	Same	Stainless steel	Same
Electrode Placement	Vaginal	Same	Anal	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
Indications for use	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles.	Same	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles.	Same

Different Features Assessment

As listed in comparison table, the following feature is different:

1. Electrode orientation : Model Fuji-01/ 02/ 11/ 12/ 14/ 15 of subject device provide the shell type of orientation, Model Fuji-03/ 04/ 05/ 06/ 07/ 08/ 09/ 10/ 13 and the predicate device provide circular type of orientation.
2. Device connector: For Fuji Dynamics Probes, the connector provided is the cord with custom designed plug. But for the predicate device, only the cord with standard 2.0 mm plug is to be provided.
3. The dimensions of the device is different as the following table :

E. 510 (k) Summary (per 21 CFR 807.92)**For Vaginal Probe :**

Model	Probe Length (cm)	Probe Diameter (cm)	Electrode Spacing (cm)	Active Surfaces, Area (cm ² / band)
Predicate Device				
Hollister K971541	5.8	2.1	1.3	5.8
Subject Devices				
FUJI-01	8.0	2.8	1.4	4.1
FUJI-02	8.0	2.8	1.4	3.9
FUJI-03	15.9	2.8	1.5	7.9
FUJI-04	10.0	2.5	1.8	7.9
FUJI-05	14.5	2.5	0.5	7.9
FUJI-06	12.0	2.5	0.4	7.9
FUJI-07	5.6	2.0	2.2	6.3
FUJI-14	7.8	3.4	2.9	3.1
FUJI-15	8.6	2.4	1.6	2.4

For Anal Probe :

Model	Probe Length (cm)	Probe Diameter (cm)	Electrode Spacing (cm)	Active Surfaces, Area (cm ² / band)
Predicate Device				
Hollister K990456	5.8	1.1	0.6	2.3
Subject Devices				
FUJI-08	8.5	1.4	0.8	1.8
FUJI-09	10.3	1.6	0.3	3.1
FUJI-10	10.3	1.6	1.1	3.1
FUJI-11	8.8	1.8	0.3	8.5
FUJI-12	12.9	1.8	0.3	8.5
FUJI-13	6.4	1.6	0.6	1.6
FUJI-14	7.8	3.4	2.9	3.1
FUJI-15	8.6	2.4	1.6	2.4

Since most of significant features of the predicate device and the subject devices as the following listing are completely identical, we considered it is reasonable to claim substantial equivalence between the subject devices

- Usage conditions

E. 510 (k) Summary (per 21 CFR 807.92)

- Body Material
- Electrode (conductive) material
- Electrode placement
- Contact duration
- Indication for use.

7. Non-clinical Testing

Biocompatibility test was conducted on Fuji Dynamics Incontinence Stimulation Electrode Fuji-01 according to

- ISO 10993, International Standards Organization (ISO) Standard.

Based upon the test results, the materials used to fabricate Fuji Dynamics Incontinence Stimulation Electrodes are biocompatible and appropriate for their intended use.

8. Clinical Test

No clinical test was conducted on Fuji Dynamics Incontinence Stimulation Electrode.

9. Sterilization

The electrodes do not require sterilization, but requires washing and drying between uses.

10. Conclusion

Based upon the information presented above, the Fuji Dynamics Incontinence Stimulation Electrode has the same intended use and technological characteristics as the predicate device of Hollister Vaginal Stimulation/EMG Probe-Tampon Stimulation/EMG Probe-Tampon (K971541) and Anal Stimulation/EMG Probe-w/Stop (K990456). The differences between the subject devices and the predicate devices do not raise question in safety and effectiveness. Therefore, it is concluded that Fuji Dynamics Incontinence Stimulation Electrodes are substantial equivalent to the predicate device.