DEC 2 1 2012

510(k) SUMMARY

[As required by 21CFR 807.92]

FDES101(ED401) Series Electro-Stimulator, K ( )

1. Submitter's Information [21CFR 807.92(a)(1)]

Company Name: Famidoc Technology Co., Ltd
Street Address: East 2/F Zhixiang Building, 71 Block Baoan District
City: Shenzhen
State/ Province: Guangdong
Country: China
Telephone: +86(755) 27864342
Fax: +86(755) 27864151
Contact Person: Cao Liang
Contact Title: General Manager
Contact Email: leon@famidoc.com

2. Trade Name, Common Name, Classification [21CFR 807.92(a)(2)]

a) **Trade Name:** FDES101(ED401) TENS and EMS Stimulator
Common Name: Electro-Stimulator or Electrical Stimulator
Classification Name: Stimulator, Muscle, Powered per 21 CFR § 890.5850;
Stimulator, Nerve, Transcutaneous. For pain relief per 21 CFR § 882.5890
Device Class: Class II
Product Code: IPF, GZJ

a) **Trade Name:** FDES102(ED402) TENS Stimulator
Common Name: TENS or TENS Device
Classification Name: Stimulator, Nerve, Transcutaneous. For pain relief

per 21 CFR § 882.5890

Device Class: Class II

Product Code: GZJ

b) Trade Name: FDES103(ED403) TENS Stimulator

Common Name: EMS or EMS Device

Classification Name: Stimulator, Muscle, Powered per 21 CFR § 890.5850;

Device Class: Class II

Product Code: IPF

a) Identification of Predicate Device(s)[21 CFR 807.92(a)(3)]

PREDICATE DEVICES	
Manufacturer	Shenzhen Dongdixin Technology Co., Ltd
Legally Marketed Device	MT9000 Series Electro-Stimulator
510 (K) Number	K093138

There are basically the same between the FDES101(ED401) Series Electro-Stimulator and the predicate device which would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use. The detailed differences between them please see below:

No.	Comparison item	New device	Predicate device	Judgment
1	510K#	K113010	K093138	--
2	Device Name	FDES101(ED401) TENS and EMS Stimulator, FDES102(ED402) TENS Stimulator, FDES103(ED403) EMS Stimulator	MT9000 Combo TENS/EMS/IF/MIC Stimulator MT9001 TENS Stimulator MT9002 EMS Stimulator MT9003 IF Stimulator MT9004 MICROCURRENT Stimulator	--
3	Manufacturer	Famidoc Technology Co., Ltd.	Shenzhen Dongdixin Technology Co., Ltd.	--
4	Power Source	DC 6V, 4×1.5V AAA batteries	9V Battery	SE
4.1	-Method of Line current isolation	Battery Supply N/A	Battery Supply N/A	--
4.2	- Patient Leakage Current -Normal condition -Single fault condition	3.0uA 5.8uA	0.61uA 0.68uA	SE, meet the requirements of IEC 60601-1
5	Classification			--
5.1	Type of protection against electric shock	Internally powered equipment	Internally powered equipment	SE
5.5	Degree of protection against electric shock	Type BF applied part	Type BF applied part	SE
5.3	Device Class	Class II	Class II	SE
6	Number of treatment programs	FDES101(ED401) 30 FDES102(ED402) 15 FDES103(ED403) 15	MT9000 4 MT9001 1 MT9002 1 MT9003 1 MT9004 1	--

No.	Comparison item	New device	Predicate device	Judgment
7	Number of Output Channels	2	2	SE
7.1	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating	SE
7.2	- Method of Channel Isolation?	By electrical circuit and software	By electrical circuit and software	SE
8	Constant Current? Constant Voltage?	Yes No	Yes No	SE
9	Software/Firmware/ Microprocessor Control?	Yes	Yes	SE
10	Automatic Overload Trip? Automatic Over Current Trip?	Yes Yes	Yes Yes	SE
11	Automatic No Load Trip?	Yes	Yes	SE
12	Automatic Shut off?	Yes	Yes	SE
13	Patient Override Control?	No	No	SE
14	Indication function			--
14.1	-On/Off Status?	Yes	Yes	SE
14.2	-Voltage/Current Level?	Yes	Yes	SE
14.3	-Low Battery?	Yes	Yes	SE
15	Timer Range (minutes)	0-60 minutes	0-60 minutes	SE
16	Housing materials	Plastic (ABS) enclosure	Plastic (ABS) enclosure	SE
17	Target population	Patients who need physiotherapy treatment	Patients who need physiotherapy treatment	SE
18	Performance	Use friendly interface, easy to operate	Use friendly interface, easy to operate	SE
19	Treatment area	Any area (Except those treatment area which been described in the user manual can not use)), such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, back and low back etc.	Any area (Except those treatment area which been described in the user manual can not use)), such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, back and low back etc.	SE

No.	Comparison item	New device	Predicate device	Judgment
20	List of patient contacting material(s)	Electrode – Transparent silica gel (same supplier TOP-RANK) Electrode cord – PVC Enclosure – ABS (AG15A1) Belt clip -- ABS(AG15A1)	Electrode – Transparent silica gel (same supplier TOP-RANK) Electrode cord – PVC Enclosure – ABS (AG15A1) Belt clip – ABS (AG15A1)	SE
20.1	Electrode lead wires	Compliance with 21CFR 898, PVC plug:φ 2mm, L=1.15m, please see the page 16 clause 7 Electrode cords of Section-08-01 Device Description for detailed.	Compliance with 21CFR 898, PVC plug:φ 2mm,L=1.5m	SE
20.2	Electrode pads	Compliance with ISO 10993-1, provided by TOP-RANK. 50*50mm, Transparent silica gel	Compliance with ISO 10993-1, provided by TOP-RANK. 40*40mm, Transparent silica gel	SE
21	Standards			--
21.1	Biocompatibility	Compliant with requirements of ISO 10993-5 and ISO 10993-10 standards	Compliant with requirements of ISO 10993-5 and ISO 10993-10 standards	SE
21.2	Mechanical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10 safety standards	Compliant with requirements of IEC 60601-1, IEC 60601-2-10 safety standards	SE
21.3	Electrical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2 safety standards	Compliant with requirements of IEC 60601-1, IEC 60601-2 -10, IEC 60601-1-2 safety standards	SE
21.4	Energy delivered	The delivered energy is limited according to requirements of collateral IEC 60601-2-10 safety standards	The delivered energy is limited according to requirements of collateral IEC 60601-2-10 safety standards	SE
22	Used at (hospital, home, ambulances)	Physiotherapy clinics	Physiotherapy clinics	SE

No.	Comparison item	New device	Predicate device	Judgment
23	Operating temperature and humidity	5-40℃ 30%-75%	5-40℃ 30%-75%	SE
24	Storage temperature and humidity	-10-50℃ 10%-90%	-10-50℃ 10%-90%	SE
25	Weight (lbs.)	0.35	0.28	SE

b) Description of Device[21 CFR 807.92(a)(4)]

The FDES101(ED401) Series Stimulator, which includes models FDES101(ED401), FDES102(ED402) and FDES103(ED403), are Transcutaneous Electrical Nerve Stimulator and muscle stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of units are controlled by the press buttons. Its intensity level is adjustable according to the needs of patients.

The three models FDES101(ED401), FDES102(ED402) and FDES103(ED403) have the same housing in a molded portable plastic case with a viewable LCD display, an accessible keypad, and accessible battery storage compartment. The case shape is rectangular. The LCD is located on the upper half of the rectangular face of the device, above the keypad. The LCD is used to display system information to the user.

The device is equipped with a keypad composed of push buttons which are located below the LCD. The function for each button is defined by a symbol on the LCD corresponding to the button immediately below it. The process to set the parameter and attach lead wires to the five models is also the same. Yet, they have different liquid crystal display and parameters for patients to create their own settings.

The FDES101(ED401) TENS and EMS Stimulator is the combination unit with the TENS, EMS functions, the function can be selected by press buttons. The range of settings is identical to those of FDES102(ED402) and FDES103(ED403). The difference on the five units can be identified by the LCD display.

c) Intended Use[21 CFR 807.92(a)(5)]

FDES101(ED401) TENS and EMS Stimulator

For TENS mode

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. post surgical pain

For EMS mode

1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

FDES102(ED402) TENS Stimulator

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

FDES103(ED403) EMS Stimulator

1. Relaxation of muscle spasm.
2. Increase of blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

d) Technological Characteristics[21 CFR 807.92(a)(6)]

a) For TENS and EMS Stimulator FDES101(ED401)

Model:	FDES101(ED401)
Use Output Channels:	Two independent output channels
Intensity:	0-60 levels adjustable
Output Amplitude:	0-60mA adjustable (at 1000ohm load)
Treatment Mode:	TENS, EMS

Pulse Width:	50-300uS
Pulse Frequency:	0.5-150Hz
Treatment Time:	1-60minutes adjustable and default 30minutes
Output Plus Wave:	Bi-phase square wave
Power Supply:	4×1.5V AAA batteries, DC 6V
Weight:	0.35 lbs (With batteries)
Device Dimensions:	129.7×76×35.1mm(L×W×H)

b) For TENS Stimulator FDES102(ED402)

Model:	FDES102(ED402)
Use Output Channels:	Two independent output channels
Intensity:	0-60 levels adjustable
Output Amplitude:	0-60mA adjustable (at 1000ohm load)
Treatment Mode:	TENS
Pulse Width:	50-300uS
Pulse Frequency:	0.5-150Hz
Treatment Time:	1-60minutes adjustable and default 30minutes
Output Plus Wave:	Bi-phase square wave
Power Supply:	4×1.5V AAA batteries, DC 6V
Weight:	0.35 lbs (With batteries)
Device Dimensions:	129.7×76×35.1mm(L×W×H)

c) For EMS Stimulator FDES103(ED403)

Model:	FDES103(ED403)
Use Output Channels:	Two independent output channels
Intensity:	0-60 levels adjustable
Output Amplitude:	0-60mA adjustable (at 1000ohm load)
Treatment Mode:	EMS
Pulse Width:	50-300uS
Pulse Frequency:	1-150Hz
Treatment Time:	1-60minutes adjustable and default 30minutes
Output Plus Wave:	Bi-phase square wave
Power Supply:	4×1.5V AAA batteries, DC 6V
Weight:	0.35 lbs (With batteries)
Device Dimensions:	129.7×76×35.1mm(L×W×H)

e) Biocompatibility Certification

Electrodes to be provided with this device are from the manufacturer Top-Rank Health Care Equipment Co., Ltd (K070612) who submitted in 2007.

The shell of device is used ABS material; this material has passed Biocompatibility testing in Guanzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration, Report No: RZ106309.

f) Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows

The FDES101(ED401) Series Electro-Stimulator did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Nonclinical testing was performed in order to validate the design according with the company's specified design requirements, and to assure conformance with the following voluntary design standards:

- IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety".
- IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility- Requirements and tests, Interpretation Sheet."
- IEC 60601-1-4 "Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
- IEC 60601-2-10 "Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators"

g) Conclusions

The FDES101(ED401) Series Stimulator, which includes models FDES102(ED402) and FDES103(ED403), has the same intended use and technological characteristics as the predicate device of MT9000 Series Electro-Stimulator, Model MT9000. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the FDES101(ED401) Series Electro-Stimulator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Famidoc Technology Co., Ltd.
% Cao Liang
East 2/F, Zhixiang Building
71 Block Baoan District
Shenzhen, Guangdong
China 518101

Re: K113010
Trade/Device Name: FDES101 (ED401) TENS and EMS Stimulator,
FDES102 (ED402) TENS Stimulator,
FDES103 (ED403) EMS Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: November 28, 2012
Received: November 28, 2012

Dear Cao Liang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Victor Krauthamer -A

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K113010

Device Name: FDES101(ED401) TENS and EMS Stimulator, FDES102(ED402) TENS Stimulator, FDES103(ED403) EMS Stimulator

Indications for Use:

FDES101(ED401) TENS and EMS Stimulator

For TENS mode

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

For EMS mode

1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

FDES102(ED402) TENS Stimulator

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

FDES103(ED403) EMS Stimulator

1. Relaxation of muscle spasm.
2. Increase of blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education

5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Prescription Use__√__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and Physical Medicine Devices
510(k) Number: K113010