
510(k) SUMMARY

[As required by 21CFR 807.92]

FEB - 7 2014

FDES106(ED406) Series Electro-Stimulator, K (130723)

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

Company Name: Famidoc Technology Co., Ltd
Street Address: No. 212 Yilong Road, Hexi Industrial Zone, Jingxia, Changan
Town
City: Dongguan
State/ Province: Guangdong
Country: China
Telephone: +86(769) 89272488-8674
Fax: +86(769) 89272498
Contact Person: Reanny Wang
Contact Title: Vice-general Manager
Contact Email: qa@famidoc.com

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

a) **Trade Name:** FDES106(ED406) Mini TENS&EMS Device
FDES106A(ED406A) Multi-function TENS&EMS Device
Common Name: Electro-Stimulator or Electrical Stimulator
Classification Name: Stimulator, Muscle, Powered, for muscle conditioning
per 21 CFR § 890.5850;
Transcutaneous Electrical Nerve Stimulator for Pain Relief;
Stimulator, Nerve, Transcutaneous, Over-the-Counter
per 21 CFR § 882.5890
Device Class: Class II
Product Code: NUH, NGX

- b) Trade Name:** FDES105(ED405) Pain Relief Plaster
Common Name: TENS or TENS Device
Classification Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief; Stimulator, Nerve, Transcutaneous, Over-the-Counter per 21 CFR § 882.5890
Device Class: Class II
Product Code: NUH
- c) Trade Name:** FDES107(ED407) Abdominal Fitness Belt
Common Name: Powered Muscle Stimulator, OTC
Classification Name: Stimulator, Muscle, Powered, for muscle conditioning per 21 CFR § 890.5850;
Device Class: Class II
Product Code: NGX

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

PREDICATE DEVICES		
Manufacturer	Endurance Therapeutics	Bio-Medical Research Ltd
Legally Marketed Device	T1040™	Slenderton FLEX Abdominal Training system type 515
510 (K) Number	K060846	K030708

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

The FDES106(ED406) Series Stimulator, which includes models FDES106(ED406), FDES106A(ED406A), FDES105(ED405) and FDES107(ED407), 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 device unit of FDES106(ED406) and FDES106A(ED406A) are same, only the applied part are different: the applied part of FDES106(ED406) is electrode pad; the applied part of FDES106A(ED406A) is electrode belt. They are portable device, battery powered (3.0V DC) multi-function device offering both Transcutaneous Electrical Nerve Stimulator(TENS) and Powered Muscle Stimulator (EMS) qualities in one device.

The FDES106 (ED406) includes FDES105 (ED405). FDES106 (ED406) has TENS and EMS two treatment mode 5 programs (N, B, H, E1, E2), FDES105 (ED405) only has TENS mode 5 treatment programs (N1, N2, B, H, F). Their appearance, structure, circuit, software operation is exactly the same, only different output treatment procedure.

FDES107 (ED407) has 10 EMS treatment process, whose intended use, waveform characteristics and is basically the same as FDES106 (ED406) EMS model, The difference is from only operation mode and structure appearance.

Independent channel (by electrode pad or electrode belt) that effectively transfers your desired choice of pre-programmed electrical pulses directly through electrode(electrode pad or electrode belt) to suggested area of the body where the electrode are placed, causing minimal muscle contractions. The FDES106 (ED406) and FDES106A (ED406A) have 3 TENS programs and 2 EMS programs; FDES105 (ED405) have 5 TENS programs; FDES107 (ED107) have 10 EMS programs.

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

FDES106(ED406) Mini TENS &EMS Device

For program N, B and H of TENS mode

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

For program E1 and E2 of EMS mode

Used to stimulate healthy muscles in order to improve and facilitate muscle performance.

FDES106A(ED406A) Multi-function Mini TENS &EMS Device***For program N, B and H of TENS mode***

To be used for temporary relief of pain associated with sore and aching muscles in the lower back, abdomen, thigh and arm due to strain from exercise or normal household work activities.

For program E1 and E2 of EMS mode

Used to stimulate healthy muscles in the lower back, abdomen, thigh and arm in order to improve and facilitate muscle performance.

FDES105(ED405) Pain Relief Plaster

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

FDES107(ED407) Abdominal Fitness Belt

Used to stimulate healthy muscles in order to improve and facilitate muscle performance for abdominal.

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows: [21 CFR 807.92(a)(6)]

The FDES106(ED406) 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 60601-1-11, 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.

- 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
- In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

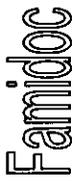
7. Biocompatibility Certification for accessories [21 CFR 807.92(a)(7)]

The materials of applied part are Electrode pad and Electrode belt; the material of enclose is ABS. They are both meet the biocompatibility testing of ISO 10993-5 and ISO 10993-10 standards.

8. Comparison for Predicate Device & Subject Device [21 CFR 807.92(a)(8)]

We present the relevant information for the predicate device here for demonstrating the characteristics of the predicate device.

8.1 Comparison of significant device features



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Date: Feb.7, 2014

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
510K#	Pending				K060846	K030708
Manufacturer	Famidoc Technology Co., Ltd.				Endurance Therapeutics	Bio-Medical Research Ltd
Prescription or OTC	OTC				OTC	OTC
FDA product code	NUH, NGX	NUH	NGX	NUH, NGX	NGX	NGX
Power source	Battery powered, d.c. 3.0V, 2 X AAA batteries				Battery powered, d.c. 4.5V, 3 X AAA batteries	
User interface	By LED light and silk-screen indication				By LCD display	
Output channel	Single channel				Two channels	
Number of output models	TENS and EMS	TENS	EMS	TENS and PMS(EMS)	EMS	EMS
Number of treatment programs	5	5	10	10	7	7
Number of output channels	Synchronous or Alternating?				Symmetrical Biphasic	
Number of output channels	1				1	
Method of channel isolation	By electrical circuit and software				By electrical circuit and software	
Constant Current or Constant Voltage?	Constant Voltage				Constant Voltage	
Waveform	Biphasic square				Biphasic	
Software/Firmware/ Microprocessor Control?	Yes				Yes	



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Data: Feb.7, 2014

Comparison item	New device			Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™ Slenderton FLEX Abdominal Training system type 515
Automatic overload trip?	Yes			Unknownable	Unknownable
Automatic Over Current Trip?	Yes			Unknownable	Unknownable
Automatic No Load Trip?	Yes			Yes	Yes
Automatic shut off?	Yes			Yes	Yes
Patient Override Control?	Yes			Yes	Unknownable
Indication function	On/off status?			Yes	Yes
	Low battery?			Yes	Yes
Voltage/ current level?	No			Yes	Yes
	Nonadjustable 30 minutes			Nonadjustable, 20, 25 and 30min	Nonadjustable, 20, 25 & 30
Patient Leakage Current	- Normal condition (uA)			0.9	0.8
	- Single fault condition (uA)			0.8	1.26
Average DC current through electrodes when device is on but no pulses are being applied (uA)	TENS: 0 EMS: 0 No output no pulse applied		TENS: 0 EMS: N/A No output no pulse applied	TENS: 0 EMS: 0 No output no pulse applied	ENS: N/A EMS: 0 No output no pulse applied
	Plastic (ABS) enclosure			Plastic (ABS) enclosure	
Housing materials construction	Plastic (ABS) enclosure			Plastic (ABS) enclosure	

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
Treatment area	For TENS mode: Low back, upper extremities(arm), Lower extremities (leg); For EMS: Any area (Except those treatment area which been described in the user manual can not use)	Arm, Waist, Buttock, Abdomen, Thigh and low back	Low back, upper extremities(arm), Lower extremities (leg);	Abdomen	For TENS mode: Low back, upper extremities(arm), Lower extremities (leg); For EMS: Any area (Except those treatment area which been described in the user manual can not use)	Abdomen
List of patient contacting material(s)	Electrode – Transparent silica gel Enclosure – ABS	Electrode belt– Silicon rubber, Cloth Enclosure – ABS	Electrode – Transparent silica gel Enclosure – ABS	Electrode belt– Silicon rubber, Cloth Enclosure – ABS	Electrode – Transparent silica gel Enclosure – ABS	Electrode belt –Transparent silica gel Enclosure – ABS
Compliance with 21 CFR 898?	Yes					



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Data: Feb.7, 2014

Comparison item	New device			Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	Slenderton FLEX Abdominal Training system type 515
Classification	Type of protection against electric shock	Internally powered equipment			Internally powered equipment
	Degree of protection against electric shock	Type BF applied part			Type BF applied part
Compliance with Voluntary Standards?	Device Class	Class II			Class II
	Biocompatibility	Compliant with requirements of ISO 10993-5 and ISO 10993-10			Same
	Mechanical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10			Same
	Electrical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2 safety standards			Same
	Energy delivered	The delivered energy is limited according to requirements of collateral IEC 60601-2-10 safety standards			Same
Applied part	Other	Compliant with requirements of IEC 60601-11 safety standard			Unknownable
	Electrode pad	Electrode belt	Electrode pad	Abdominal electrode belt	Abdominal electrode belt
Weight (lbs., oz.)	0.093	0.093	0.093	0.18	0.19
Dimensions (in.) [W x H x D] For unit	2.25" x 1.77" x 0.36"		3.62" x 3.19" x 0.75"		5.91" x 2.68" x 1.02"

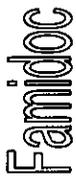


Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Data: Feb.7, 2014

Comparison item	New device			Predicate device		
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
Operating temperature and humidity	5-40°C, 30%-85%			Unknownable		0-35°C, 20%-65%
Storage temperature and humidity	-10-50°C, 10%-90%			Unknownable		0-52°C, 10%-90%

8.2 Comparison of significant output specifications:

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
Waveform	TENS mode	Biphasic	Biphasic	N/A	Biphasic	N/A
	EMS mode	Biphasic	N/A	Biphasic	Biphasic	Biphasic
Shape	TENS mode	Square	Square	N/A	Square	N/A
	EMS mode	Square	N/A	Square	Square	Square
Max Output Voltage (V)						
	TENS mode	30.4	30.4	28	N/A	40.7
	EMS mode	28	28	N/A	46.4	40.7
	TENS mode	44.8	44.8	36.8	N/A	105.1
	EMS mode	44.8	44.8	N/A	72	105.1
						89.3



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Data: Feb.7, 2014

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
10kΩ load	TENS mode	54.4	41.6	N/A	154.1	N/A
	EMS mode	54.4	N/A	120	154.1	91.3
Max Output Current (mA)						
500Ω load	TENS mode	60.8	56	N/A	81.4	N/A
	EMS mode	56	N/A	92.8	81.4	94.7
2kΩload	TENS mode	22.4	18.4	N/A	47.8	N/A
	EMS mode	22.4	N/A	36	47.8	89.3
10kΩ load	TENS mode	5.4	4.2	N/A	15.4	N/A
	EMS mode	5.4	N/A	12	15.4	60.7
Pulse Width Range(μS)	TENS mode	200-250	200-250	N/A	4.1-500	N/A
	EMS mode	250	N/A	250	4.1-500	200-300
Frequency(Hz)	TENS mode	2-80	2-80	N/A	245	N/A
	EMS mode	2-50	N/A	3-80	245	45-75
Net Charge per pulse cycle (μC, 500Ω)	TENS mode	15.2	15.2	N/A	40.7	N/A
	EMS mode	14	N/A	23.2	40.7	28.41
Maximum Phase Charge (μC, 500Ω)	TENS mode	15.2	15.2	N/A	2.71	N/A
	EMS mode	14	N/A	23.2	2.71	Unknowable



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Date: Feb.7, 2014

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
Maximum Current Density (mA/cm ² , 500Ω, r.m.s)	4.1	3.4	4.1	N/A	2.71	N/A
Maximum Average Current (average absolute value) [mA, 500Ω]	3.77	3.13	N/A	1.9	2.71	Unknownable
Maximum Power Density (W/cm ² , 500Ω, r.m.s)	0.51	0.42	0.48	N/A	Unknownable	N/A
Maximum Average Power Density (mW/cm ²) [using smallest electrode conductive surface area]	0.41	0.34	N/A	0.3	Unknownable	Unknownable
Duration of primary (depolarizing) phase (ms)	0.124	0.103	0.105	N/A	0.099	N/A
Burst Mode (For TENS mode only)	0.105	0.087	N/A	0.039	0.099	Unknown
a. Pulse per burst	2	1.4	1.7	N/A	5.35	N/A
b. Bursts per second	1.2	1	N/A	1.8	5.35	Unknownable
c. Burst duration (ms)	0.25	0.25	0.25	N/A	0.5	N/A
d. Duty Cycle (ms)	0.25	0.25	N/A	0.25	0.5	0.3
	7	7	7	N/A	N/A	N/A
	2	2	2	N/A	N/A	N/A
	0.2	0.2	0.2	N/A	N/A	N/A
	1.4	1.4	1.4	N/A	N/A	N/A



Sponsor: Famidoc Technology Co., Ltd.
 File No: XW-Stimulator A-FDA-07
 Version: 1.2
 Date: Feb.7, 2014

Comparison item	New device				Predicate device	
	Mini TENS & EMS Device FDES106	Multi-function Mini TENS & EMS Device FDES106A	Pain Relief Plaster FDES105	Abdominal Fitness Belt FDES107	T1040™	Slenderton FLEX Abdominal Training system type 515
For EMS mode only						
On Time (S)	5	5	N/A	4-8	N/A	Unknownable
Off Time (S)	10	10	N/A	2-10	N/A	Unknownable
Ramp up time(S)	2	2	N/A	2-10	N/A	Unknownable
Ramp down time(S)	2	2	N/A	0-12	N/A	Unknownable

9. Conclusions

The FDES106(ED406) Series Stimulator, which includes models FDES105(ED405), FDES106A(ED406A) and FDES107(ED407), has the same intended use and technological characteristics and the similar technological characteristics as the predicate device T1040 (K060846) and Slenderton FLEX Abdominal Training system type 515 (K030708). 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 FDES106(ED406) Series Electro-Stimulator is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Famidoc Technology Co., Ltd.
c/o Reanny Wang
Vice-General Manager
No. 212 Yilong Road, Hexi Industrial Zone, Jingxia,
Changan Town, Dongguan 523853,
Guangdong Province
CHINA

Re: K130723

Trade Name: FDES106 (ED406) Series OTC Stimulator Models:
Mini TENS&EMS Device Model FDES106 (ED406),
Multi-function Mini TENS&EMS Device Model FDES106A
(ED406A), Pain Relief Plaster Model FDES105 (ED405),
Abdominal Fitness Belt Model FDES107 (ED407)

Regulation Number: 21 CFR 890.5850

Regulation Name: Powered Muscle Stimulator

Regulatory Class: Class II

Product Code: NGX, NUH

Dated: January 7, 2014

Received: January 13, 2014

Dear Mr. Wang:

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 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>. 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,

Carlos L. Peña-S

Carlos L. Peña, PhD, MS
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: K130723

Device Name: FDES106 Series OTC Stimulator Models:
Mini TENS&EMS Device Model FDES106 (ED406),
Multi-function Mini TENS&EMS Device Model FDES106A (ED406A),
Pain Relief Plaster Model FDES105 (ED405),
Abdominal Fitness Belt Model FDES107 (ED407),

Indications For Use:

FDES106 (ED406) Mini TENS &EMS Device

For program N1, B and H of TENS mode

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

For program E1 and E2 of EMS mode

Used to stimulate healthy muscles in order to improve and facilitate muscle performance.

FDES106A (ED406A) Multi-function Mini TENS &EMS Device

For program N1, B and H of TENS mode

To be used for temporary relief of pain associated with sore and aching muscles in the lower back, abdomen, thigh, and arm due to strain from exercise or normal household work activities.

For program E1 and E2 of EMS mode

Used to stimulate healthy muscles in the lower back, abdomen, thigh, and arm in order to improve and facilitate muscle performance.

FDES105 (ED405) Pain Relief Plaster

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

FDES107 (ED407) Abdominal Fitness Belt

Used to stimulate healthy muscles in order to improve and facilitate muscle performance for abdominal.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Carlos L. Peña -S