January 11, 2020

ASTEK Technology Ltd.
You-Jhe Lin
Engineer
No. 118 Taizih Rd., Rende Dist
Tainan City, 71741 Taiwan

Re: K183074
Trade/Device Name: TENS and EMS Stimulator, TENS Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: December 10, 2019
Received: December 13, 2019

Dear You-Jhe Lin:

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,

For Vivek Pinto, Ph.D.
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K183074

Device Name
TENS and EMS Stimulator, TENS Stimulator

Indications for Use *(Describe)*

TENS Stimulator (Model no.: AK-10M)
TENS Stimulator provides 5 types TENS output modes (P1-P5)
For TENS mode
(1) Symptomatic relief of chronic intractable pain, (2) Post traumatic pain, (3) Post-surgical pain

TENS and EMS Stimulator (Model no.: AK3-20 and AK3-25)
TENS and EMS Stimulator provides 8 types output modes (P1-P8). TENS/EMS output modes (P1-P6&P8) and TENS output modes (P7)
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 muscles to prevent venous thrombosis

TENS and EMS Stimulator (Model no.: AK3-50)
TENS and EMS Stimulator provides 10 types output modes (P0-P9). TENS output modes (P0-P4) and EMS output modes (P5-P9)
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 muscles to prevent venous thrombosis

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.

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 01/11/2020

5.3 Submitter: ASTEK Technology Ltd.

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Phone:	+886-6-2729488
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Contact:	You-Jhe Lin (rd@astek-health.com)

5.4 Identification of the Device:

Proprietary/Trade name:	TENS and EMS Stimulator, TENS Stimulator
Regulation Description:	Powered muscle stimulator.
Review Panel:	Physical Medicine
Regulation Number:	890.5850
Device Class:	II
Primary Product Code	IPF
Subsequent Product Code	GZJ

5.5 Identification of the Predicate Device (K113010)

Predicate Device Name:	FDES 101 (ED401) TENS and EMS Stimulator, FDES 102 (ED402) TENS Stimulator, FDES 103 (ED403) EMS Stimulator
Manufacturer:	Famidoc Technology Co., Ltd
Regulation number:	890.5850
Device Class:	II
Primary Product Code	IPF
Subsequent Product Code	GZJ

5.5 Intended Use

- **TENS Stimulator (Model No.: AK-10M)**

  TENS Stimulator provides 5 types TENS output modes (P1-P5)

  For TENS mode

  (1) Symptomatic relief of chronic intractable pain, (2) Post traumatic pain, (3) Post-surgical pain

- **TENS and EMS Stimulator (Model No.: AK3-20, AK3-25)**

  TENS and EMS Stimulator provides 8 types output modes (P1-P8). TENS/EMS output modes (P1-P6&P8) and TENS output modes (P7)

  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 postsurgical stimulation of muscles to prevent venous thrombosis

- **TENS and EMS Stimulator (Model No.: AK3-50)**

  TENS and EMS Stimulator provides 10 types output modes (P0-P9). TENS output modes (P0-P4) and EMS output modes (P5-P9)

  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 postsurgical stimulation of muscles to prevent venous thrombosis

5.6 Device description

- **TENS Stimulator (Model No.: AK-10M) and EMS Stimulator (Model No.: AK3-20, AK3-25 and AK3-50)**

The TENS stimulator and TENS and EMS stimulator, are Transcutaneous Electrical Nerve Stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulators send gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of devices are controlled by the press buttons. Its intensity level is adjustable according to the needs of patients.

The four models have similar housing in a molded plastic case with viewable LCD display, an accessible keypad, and accessible battery storage compartment. 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 that control the program selection, strength, channel, and power.

The TENS and EMS Stimulator (Model No.: AK3-20, AK3-25 and AK3-50) is the comination unit with the TENS and EMS functions; the function can be selected by press buttons. The range of settings is identical in models AK3-20 and AK3-25 while model AK3-50 provides 10 types of output modes.

5.7 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, TENS and EMS Stimulator, TENS Stimulator.

- Shelf life test
- Software validation
- EMC and Electrical Safety test
- Performance test

All the test results demonstrate that TENS and EMS Stimulator, TENS Stimulator meets the requirements of its pre-defined acceptance criteria, and is substantially equivalent to the predicate device.

5.8 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.9 Substantial Equivalence Determination

The TENS and EMS Stimulator, TENS Stimulator has the same intended use, and technological characteristics with the predicate device (K113010). A series of tests were performed and demonstrated substantial equivalence between the subject and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Subject device	Predicate device	Substantially equivalence
Proprietary Name	TENS and EMS Stimulator, TENS Stimulator	FOES 101 (ED401) TENS and EMS Stimulator, FOES 102 (ED402) TENS Stimulator, FOES 103 (ED403) EMS Stimulator	-
510(k) No.	K183074	K113010	-
Model number	AK-10M, AK3-20, AK3-25, AK3-50	FOES101 (ED401)	-
Manufacturer	ASTEK Technology Ltd.	Famidoc Technology Co., Ltd	-
Prescription or OTC	Prescription	Prescription	Same
Regulation Number	890.5850	890.5850	Same
Product code	IPF, GZJ	IPF, GZJ	Same
Intended Use	**TENS Stimulator (Model No.: AK-10M)** TENS Stimulator provides 5 types TENS output modes (P1-P5) For TENS mode (1) Symptomatic relief of chronic intractable pain, (2) Post traumatic pain, (3) Post-surgical pain **TENS and EMS Stimulator (Model**	**FDES 101 (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	Same

Item	Subject device	Predicate device	Substantially equivalence
	No.: AK3-20, AK3-25) TENS and EMS Stimulator provides 8 types output modes (P1-P8). TENS/EMS output modes (P1-P6&P8) and TENS output modes (P7) 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 postsurgical stimulation of muscles to prevent venous thrombosis **TENS and EMS Stimulator (Model No.: AK3-50)** TENS and EMS Stimulator provides 10 types output modes (P0-P9). TENS output modes (P0-P4) and EMS output modes (P5-P9) For TENS mode (1) Symptomatic relief of chronic intractable pain, (2) Post traumatic pain, (3) Post-surgical pain For EMS mode	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	

Item	Subject device	Predicate device	Substantially equivalence
	(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 postsurgical stimulation of muscles to prevent venous thrombosis		
Using Environment	Physiotherapy clinics	Physiotherapy clinics	Same
Target population	Patients who need physiotherapy treatment	Patients who need physiotherapy treatment	Same
Treatment area	Neck / Shoulders, Waist/ Abdomen, Arms and Hands, Legs and Feet	Any area (Except those treatment area which been described in the user manual can't use), such as hand, arm, chest, waist, buttock, thigh, calf, back and low back etc.	Same
Program	**Model no.:** AK-10M - Mode: TENS - Consisting of a monophasic waveform with a different range of output voltages, pulse durations, frequencies **Model no.:**AK3-20 - Mode: TENS or TENS/EMS - Consisting of a biphasic waveform with a different range of output voltages, pulse durations, frequencies, etc. **Model no.:**AK3-25 - Mode: TENS or TENS/EMS - Consisting of a biphasic waveform	- Not publicly available	Similar

Item	Subject device	Predicate device	Substantially equivalence
	with a different range of output voltages, pulse durations, frequencies, etc. **Model no.:** AK3-50 - Mode: TENS or TENS/EMS - Consisting of a biphasic waveform with a different range of output voltages, pulse durations, frequencies, etc.		

Basic Unit Characteristics

Item	Subject Device				Predicate device	Substantially equivalence
Model	**AK-10M**	**AK3-20**	**AK3-25**	**AK3-50**	**FOES101 (ED401)**	**-**
Type of use	Prescription Use				Prescription Use	Same
Power source	DC 3V 1xCR2032 battery	DC 3V 1xCR2032 battery	DC 3V 1xCR2032 battery	DC 6V 4xAA batteries	DC 6V 4xAAA batteries	Different
Method of Line Current Isolation	N/A	N/A	N/A	N/A	N/A	Same
Patient Leakage Current - **Normal condition** - **Single fault condition**	 0.1μA N/A	 0.1μA N/A	 0.1μA N/A	 0.1μA N/A	 3.0 μA 5.8 μA	Different
Note: Although the "Power Source" and "Patient Leakage Current" of subject device are little different from the predicate devices, they all comply with IEC 60601-1 requirements. So the slight differences will not affect the safety and effectiveness of subject device.						
Number of Output Modes - **TENS** - **EMS** - **TENS/EMS**	 5 N/A N/A	 1 N/A 7	 1 N/A 7	 5 N/A 5	 15 15 N/A	Similar
Number of output channels - **Synchronous or Alternating** - **Method of Channel Isolation**	1 Synchronous and Alternating	1 Synchronous and Alternating	2 Synchronous and Alternating	4 Synchronous and Alternating	2 Synchronous and Alternating	Different Same Same

Item	Subject Device				Predicate device	Substantially equivalence
Model	**AK-10M**	**AK3-20**	**AK3-25**	**AK3-50**	**FOES101 (ED401)**	**-**
	By electrical circuit and software	By electrical circuit and software	By electrical circuit and software	By electrical circuit and software	By electrical circuit and software	
Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Not publicly available	Different
Software, Firmware, Microprocessor control	Yes	Yes	Yes	Yes	Yes	Same
Automatic Overload Trip?	N/A	N/A	N/A	N/A	Yes	Different
Automatic No-Load Trip?	N/A	Yes	Yes	N/A	Yes	Different
Automatic Shut Off?	Yes	Yes	Yes	Yes	Yes	Same
Patient Override Control?	N/A	N/A	N/A	N/A	N/A	Same
Indicator Display						
- **On/Off Status**	Yes	Yes	Yes	Yes	Yes	Same
- **Low Battery**	N/A	N/A	N/A	Yes	Yes	Different
- **Voltage/Current Level**	Yes	Yes	Yes	Yes	Yes	Same
Timer range	15 minutes	15 minutes	15 minutes	10-30 minutes	0-60 minutes	Different
Compliance with Voluntary Standards	IEC60601-1, IEC60601-1-2,	IEC60601-1, IEC60601-1-2,	IEC60601-1, IEC60601-1-2,	IEC60601-1, IEC60601-1-2,	IEC60601-1, IEC60601-1-2,	Same

Item		Subject Device				Predicate device	Substantially equivalence
Model		**AK-10M**	**AK3-20**	**AK3-25**	**AK3-50**	**FOES101 (ED401)**	**-**
		IEC60601-2-10, ISO10993-1	IEC60601-2-10, ISO10993-1	IEC60601-2-10, ISO10993-1	IEC60601-2-10, ISO10993-1	IEC60601-2-10, ISO10993-1	
Compliance with 21 CFR898?		Yes	Yes	Yes	Yes	Not publicly available	Same
Weight		15.5 g	80 g	106 g	282 g	0.35 lbs.	Different
Dimensions [W×H×D]		54.8×35.6×10.8	70×69×44	70×70×70 mm	137×96×41	76×129.7×35.1 mm	Different
Housing materials and construction		ABS	PMMA, ABS	PMMA and ABS	ABS	ABS	Same
Note: Although the "Number of Output Modes", "Number of Output Channels", "Automatic Overload Trip", "Automatic No-Load Trip", "Indicator Display", "Timer Range", "Weight" and "Dimensions" of subject device are different from that of the predicate devices, they all comply with IEC 60601-1, IEC60601-1-2, IEC 60601-2-10 and ISO10993-1 requirements. Hence, differences will not affect the safety and effectiveness of subject device.							
Waveform		Biphasic wave	Biphasic wave	Biphasic wave	Biphasic wave	Biphasic wave	Different
Shape (e.g., rectangular, spike, rectified sinusoidal)		Square	Square	Square	Square	Square	Different
Maximum Output Voltage	**@500Ω**	73.19 Vpp	66.4 Vpp	33.4 Vpp	73.19 Vpp	Not publicly available	Different
	@2KΩ	94.22 Vpp	107.6 Vpp	66 Vpp	52 Vpp	Not publicly available	
	@10KΩ	113.1 Vpp	129.6 Vpp	117.2 Vpp	52 Vpp	Not publicly available	
Maximum Output Current	**@500Ω**	146.38 mA	132.8 mA	66.8 mA	96 mA	Not publicly available	Different
	@2KΩ	47.11 mA	53.8 mA	33 mA	26 mA	Not publicly available	
	@10KΩ	11.31 mA	12.96 mA	11.72 mA	5.2 mA	Not publicly available	

Item	Subject Device				Predicate device	Substantially equivalence
Model	**AK-10M**	**AK3-20**	**AK3-25**	**AK3-50**	**FOES101 (ED401)**	**-**
Pulse Width	175 µS	100 µS	100 µS	125 µS	50-300µS	Different
Frequency	2-120Hz	3-50 Hz	3-50 Hz	1-50 Hz	0.5-150Hz	Different
For interferential modes only - **Beat Frequency (Hz)**	N/A	N/A	N/A	N/A	Not publicly available	Same
For multiphasic waveforms only - **Symmetrical phases** - **Phase Duration**	Yes 350 µs	N/A 200 µs	N/A 200 µs	N/A 250 µs	Not publicly available	Same Different
Net Charge (@500Ω)	24.9µC	22.8 µC	22.8 µC	23.5 µC	Not publicly available	Different
Maximum Phase Charge (@500Ω)	24.9µC	22.8 µC	22.8 µC	23.5 µC	Not publicly available	Different
Maximum Current Density, @500Ω	< 2 mA/cm²	0.204mA/cm²	0.32 mA/cm²	0.216 mA/cm²	Not publicly available	Different
Maximum Power Density, (W/cm²) r.m.s., @500Ω	0.049	0.0446	0.013	0.023	Not publicly available	Different
Burst Mode - **Pulses per burst** - **Bursts per second** - **Burst duration (seconds)** - **Duty Cycle**	 N/A N/A N/A N/A	 N/A N/A N/A N/A	 N/A N/A N/A N/A	 N/A N/A N/A N/A	Not publicly available	Different
ON Time (seconds)	N/A	N/A	N/A	N/A	Not publicly available	Different

Item	Subject Device				Predicate device	Substantially equivalence
Model	**AK-10M**	**AK3-20**	**AK3-25**	**AK3-50**	**FOES101 (ED401)**	**-**
OFF Time (seconds)	N/A	N/A	N/A	N/A	Not publicly available	Different
Electrode area	N/A	N/A	N/A	N/A	Not publicly available	Different
Note: Due to our design consideration, the “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Width”, “Frequency”, “multi-program waveforms”, “Net charge”, “Max. Phase Charge”, “Max. Current Density”, “Max. Average Power Density”, “Burst Mode”, “ON/OFF time” and “Electrode area” are not all the same as that of the predicate. However, both of comply with IEC 60601-1, IEC60601-1-2, IEC 60601-2-10 and ISO10993-1 requirements. In spite of these differences, the subject device passed the safety and performance tests. So the differences will not affect the safety and effectiveness of subject device, and not affect the substantial equivalence between these devices.						

5.10 Similarity and Differences

The subject device has same intended use and similar technological characteristics as predicate device. Difference between the subject device and predicate device are such as patient leakage current, number of output modes, number of output channels, regulated current or regulated voltage, timer range, weight, dimensions and output Specifications. Although there are some differences between subject and predicate devices, the subject device has passed a series of electrical safety and performance tests. And thus, we believe that differences between the devices cited in this section do not raise any new issues of substantial equivalence. The subject device is substantially equivalent to the predicate device in safety and performance claims.

5.11 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that TENS and EMS Stimulator, TENS Stimulator is substantially equivalent to the predicate device.