November 29, 2017

Hivox Biotek Inc.
Linda Lin
Territory Sales
5F., No. 123, Xingde Rd.
Sanchong Dist.
New Taipei City, 24158 Tw

Re: K171803
Trade/Device Name: HIVOX OTC Electrical Stimulators Model SEM44 and Model SEM44-1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: August 21, 2017
Received: August 31, 2017

Dear Linda 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.11.29 20:14:45 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*

Device Name
HIVOX OTC Electrical Stimulator (SEM44, SEM44-1)

Indications for Use *(Describe)*

HIVOX OTC Electrical Stimulator, SEM44 –
TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.
EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

HIVOX OTC Electrical Stimulator, SEM44-1 –
TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

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.

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510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: November 29, 2017

5.3 Submitter:

Address:	5F., No. 123, Xingde Rd., Sanchong Dist., New Taipei City 24158, Taiwan, R.O.C.
Phone:	+886-2-8511-2668
Fax:	+886-2-8511-2669
Contact:	Mr. Linda Lin (linda.lin@hivox-biotek.com)

5.4 Identification of the Device:

Proprietary/Trade name:	HIVOX OTC Electrical Stimulator
Model Number:	SEM44, SEM44-1
Classification Product Code:	NUH
Subsequent Product Code:	NGX
Regulation Number:	1) 882.5890 2) 890.5850
Regulation Description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator
Review Panel:	1) Neurology 2) Physical Medicine
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	OTC Electrical stimulator
Model Number:	MT9001, LT3060
Manufacturer:	Shenzhen Dongdixin Technology Co., Ltd.

Classification Product Code:	NUH
Subsequent Product Code:	NGX
Regulation number:	882.5890
Device Class:	II
510(k) Number:	K130802

Predicate Device Name:	Tyece OTC TENS Device
Model Number:	SEM44
Manufacturer:	SAVIA Ltd.
Classification Product Code:	NUH
Regulation number:	882.5890
Device Class:	II
510(k) Number:	K150386

5.6 Intended Use/ Indications for Use of the Device

HIVOX OTC Electrical Stimulator, SEM44 –
TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.
EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

HIVOX OTC Electrical Stimulator, SEM44-1 –
TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

5.7 Device Description

HIVOX OTC Electrical Stimulator – SEM44 and SEM44-1, falls into the electro stimulation device category.

SEM44 provides two basic functions, TENS/EMS; SEM44-1 provides one basic function, TENS:

1. Electrical stimulation of nerve tracts (TENS)
2. Electrical stimulation of muscle tissue (EMS)

The two models also feature two independent stimulation channels and four adhesive electrodes which FDA cleared k number is K132588. For TENS, SEM44 and SEM44-1 are designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.; For EMS, SEM44 is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. For these purposes, the user can either choose from pre-set programs or specify their own to suit the user's individual needs.

The principle of electro stimulation units is based on the imitation of impulses in our bodies that are transferred to nerve and muscle fibers with electrodes via our skin. The electrodes can be applied to many parts of the body. In certain applications the user will merely notice a slight tingling or vibrating sensation. For SEM44, the electrical impulses that are sent into the tissue influence the transmission of stimulation into nerves, nerve centers and muscle groups in the application area; for SEM44-1, the electrical impulses that are sent into the tissue influence the transmission of stimulation into nerves and nerve centers in the application area.

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, HIVOX OTC Electrical Stimulator (SEM44, SEM44-1).

- Shelf Life
- Biocompatibility
- Software Validation
- Electromagnetic compatibility and electrical safety
- Function test

All the test results demonstrate HIVOX OTC Electrical Stimulator (SEM44, SEM44-1) meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

5.9 Clinical Testing

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

5.10 Substantial Equivalence Determination

The HIVOX OTC Electrical Stimulator (SEM44, SEM44-1) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared OTC Electrical stimulator Models MT9001, LT3060 (K130802) and Tyece OTC TENS Device, Model SEM44 (K150386). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	**Subject device**		**Predicate device I**		**Substantial equivalence determination**
Proprietary Name	HIVOX OTC Electrical Stimulator		OTC Electrical stimulator		N/A
Model	SEM44	SEM44-1	MT9001	LT3060	
510(k) No.	(to be assigned)		K130802		
Intended Use	SEM44 – TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. SEM44-1 – TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the		MT9001 - TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. LT3060 - TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck,		Similar. Both devices utilize TENS to release pain associated with sore and aching muscles, and EMS to improve and facilitate muscle performance.

		shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.	
Type of use		OTC	OTC	Same
Basic Unit Characteristics				
Power Source		4.5V (batteries, 3x1.5V AAA)	9V batteries	Different but does not adversely impact safety and effectiveness of subject device
Method of Line Current Isolation		N/A	N/A	Same
Patient Leakage Current	Normal condition	N/A	0.61μA	This parameter is not applicable to subject device.
	Single fault condition	N/A	0.68μA	
Number of Output Modes		TENS: 15 EMS: 35	TENS: 15	TENS: 1 EMS: 1	Different but does not adversely impact safety and effectiveness of subject device
Number of Output Channels	Synchronous or Alternating	2 Synchronous	Alternating	Different but does not adversely impact safety and effectiveness of

				subject device
	Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software	Same
Regulated Current or Regulated Voltage?		Regulated voltage	Current control	Different but does not adversely impact safety and effectiveness of subject device
Software/Firmware/ Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip?		Yes	Yes	Same
Automatic No-Load Trip?		Yes	Yes	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status	Yes	Yes	Same
	Low Battery	Yes	Yes	Same
	Voltage/ Current Level	Yes	Yes	Same
Timer Range (minutes)		5-100 minutes	1-60 minutes	Different but does not adversely impact safety and effectiveness of subject device
Compliance with Voluntary Standards		IEC 60601-1, IEC 60601-1-2,	IEC 60601-1, IEC 60601-1-2,	Same

		IEC 60601-2-10, ISO10993-5/10	IEC 60601-2-10, ISO10993-5/10		
Compliance with 21 CFR 898-7		Yes	Yes		Same
Weight		89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	128g (including batteries)		Slightly different but does not impact safety and effectiveness of subject device
Dimensions [L x W x T]		132 x 63 x 29.5 mm (including belt clip)	117 x 60 x 34 mm		Slightly different but does not impact safety and effectiveness of subject device
Housing Materials and Construction		ABS	ABS		Same
Output Specifications					
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic		Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		Square	Square		Same
Maximum Output Voltage (Volts, Vpp)	@500Ω	100±10%	96±20% (48±20% (Vp))		Different but does not adversely impact safety and effectiveness of subject device
	@2KΩ	180±10%	200±20% (100±20% (Vp))	228±20% (114±20% (Vp))	
	@10KΩ	250±10%	210±20% (105±20% (Vp))	230±20% (115±20% (Vp))	
Maximum	@500Ω	200±10%	96±20%		Different but

Output Current (mA)	@2KΩ	90±10%	50±20%	57±20%	does not adversely impact safety and effectiveness of subject device
	@10KΩ	25±10%	10.5±20%	11.5±20%	
Duration of primary phase		50-450μS	50-300μS		Different but does not adversely impact safety and effectiveness of subject device
Pulse Duration		50-450μS	50-300μS		Different but does not adversely impact safety and effectiveness of subject device
Frequency		1-150Hz	1-150Hz		Same
For interferential modes only – Beat Frequency		N/A	N/A		Same
For multi-program waveforms only –	Symmetrical Phases?	N/A	Yes		This parameter is not applicable to subject device.
	Phase Duration	N/A	50-300μS		
Net charge (micro coulombs μC) (per pulse)		0.001μC@500Ω	0μC@500Ω		Same
method of achieving zero net charge		N/A	biphasic and leading polarity alternates for each successive, Pulse + and pulse – pulse channel		This parameter is not applicable to subject device.
Max. phase charge (mC)		0.045@500Ω	0.0288@500Ω		Different but does not

					adversely impact safety and effectiveness of subject device
Max. current Density (mA/cm², r.m.s)		0.667@500Ω	1.15@500Ω		Different but does not adversely impact safety and effectiveness of subject device
Max. Average current (average absolute value), mA		13.5@500Ω	4.32@500Ω		Different but does not adversely impact safety and effectiveness of subject device
Max. Average Power Density, W/cm² (using smallest electrode conductive surface area)		0.0046@500Ω	0.373@500Ω		Different but does not adversely impact safety and effectiveness of subject device
Burst Mode (i.e. pulse trains)	(a) Pulses per burst	3	7	N/A	Different but does not adversely impact safety and effectiveness of subject device
	(b) Bursts per second	2/60Hz	0.5/1/2/3/4/5 Hz	N/A	
	(c) Burst duration	36ms	70ms	N/A	
	(d) Duty cycle	36ms/390ms	35ms/350ms	N/A	
ON Time (seconds)		2	N/A	1-30	Similar and does not impact safety and effectiveness of subject device

OFF Time (seconds)	2	N/A	1-60	Similar and does not impact safety and effectiveness of subject device
Electrode area	20.25sqcm x4 (81sqcm)	25sqcm x2 (100sqcm)		Different but does not adversely impact safety and effectiveness of subject device
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0		Same

Item	**Subject device**	**Predicate device II**	**Substantial equivalence determination**
Proprietary Name	HIVOX OTC Electrical Stimulator	Tyece OTC TENS Device	N/A
Model	SEM44-1	SEM44	
510(k) No.	(to be assigned)	K150386	
Intended Use	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or	The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household activities.	Similar. Both devices utilize TENS to release pain associated with sore and aching muscles.

		normal household work activities.		
Type of use		OTC	OTC	Same
Basic Unit Characteristics				
Power Source		4.5V (batteries, 3x1.5V AAA)	4.5V (batteries, 3x1.5V AAA)	Same
Method of Line Current Isolation		N/A	N/A	Same
Patient Leakage Current	Normal condition	N/A	N/A	Same
	Single fault condition	N/A	N/A	
Number of Output Modes		TENS: 15	15 Modes (01-15)	Different but does not adversely impact safety and effectiveness of subject device
Number of Output Channels	Synchronous or Alternating	2 Synchronous	2 Synchronous	Same
	Method of Channel Isolation	By electrical circuit and software	PCB Insulation Boost Isolation	Different but does not adversely impact safety and effectiveness of subject device
Regulated Current or Regulated Voltage?		Regulated voltage	Regulated voltage	Same
Software/Firmware/ Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip?		Yes	No	Different but

				does not adversely impact safety and effectiveness of subject device
Automatic No-Load Trip?		Yes	Yes	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status	Yes	Yes	Same
	Low Battery	Yes	Yes	Same
	Voltage/ Current Level	Yes	Yes for voltage	Similar and does not impact safety and effectiveness of subject device
Timer Range (minutes)		5-100 minutes	5-100 minutes	Same
Compliance with Voluntary Standards		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10	Same
Compliance with 21 CFR 898-7		Yes	Yes	Same
Weight		89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	101 g (including belt chip)	Slightly different but does not impact safety and effectiveness of subject device
Dimensions [W x H x D]		132 x 63 x 29.5 mm (including belt clip)	132 x 63 x 29.5 mm (including belt clip)	Same
Housing Materials and Construction		ABS	ABS	Same

Output Specifications				
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		Square	Square	Same
Maximum Output Voltage (Volts, Vpp)	@500Ω	100±10%	70±15%	Different but does not adversely impact safety and effectiveness of subject device
	@2KΩ	180±10%	110±15%	
	@10KΩ	250±10%	190±15%	
Maximum Output Current (mA)	@500Ω	200±10%	86±15%	Different but does not adversely impact safety and effectiveness of subject device
	@2KΩ	90±10%	23.3±15%	
	@10KΩ	25±10%	3.75±15%	
Duration of primary phase		50-450μS	0	Different but does not adversely impact safety and effectiveness of subject device
Pulse Duration		50-450μS	50-360μS	Different but does not adversely impact safety and effectiveness of subject device
Frequency		1-150Hz	1-150Hz	Same
For multi-program	Symmetrical Phases?	N/A	N/A	Same

waveforms only	Phase Duration			
Net charge (micro coulombs μC) (per pulse)		0.001μC@500Ω	0.001μC @500Ω	Same
Max. phase charge (mC)		0.045@500Ω	0.0454@500Ω	Different but does not adversely impact safety and effectiveness of subject device
Max. current Density (mA/cm², r.m.s)		0.667@500Ω	0.790@500Ω	Different but does not adversely impact safety and effectiveness of subject device
Max. Average current (average absolute value), mA		13.5@500Ω	16.0@500Ω	Different but does not adversely impact safety and effectiveness of subject device
Max. Average Power Density, W/cm² (using smallest electrode conductive surface area)		0.0046@500Ω	0.00632@500Ω	Different but does not adversely impact safety and effectiveness of subject device
Burst Mode (i.e. pulse	(a) Pulses per burst	3	4	Different but does not adversely impact safety and
	(b) Bursts per second	2/60Hz	4/83Hz	
	(c) Burst duration	36ms	0.18ms	

trains)	(d) Duty cycle	36ms/390ms	35ms/60ms	effectiveness of subject device
ON Time (seconds)		2	2	Same
OFF Time (seconds)		2	2	Same
Electrode area		20.25sqcm x4 (81sqcm)	20.25sqcm x4 (81sqcm)	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)		0	0	Same

5.11 Similarity and Difference

The HIVOX OTC Electrical Stimulator (SEM44, SEM44-1) has been compared with "OTC Electrical stimulator Models MT9001, LT3060" and "Tyece OTC TENS Device, Model SEM44" respectively. The subject device has similar intended use, technological characteristics and same principle of operation as these predicate devices. Although there are several specifications that are different between two devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate devices did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate devices in intended use, safety and performance claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the HIVOX OTC Electrical Stimulator (SEM44, SEM44-1) is substantially equivalent to the predicate devices.