November 8, 2019

Hivox Biotek Inc.
Marx Lee
Regulatory Affairs Representative
5F., No. 123, Xinde Rd.
Sanchong Dist.
New Taipei City, TW 24158

Re: K192264
Trade/Device Name: HIVOX Spopad EMS SP-911, SP-921
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 7, 2019
Received: October 9, 2019

Dear Marx Lee:

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.
Acting Assistant 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)*
K192264

Device Name
HIVOX Spopad EMS SP-911, SP-921

Indications for Use *(Describe)*
These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

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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Section 6

510(k) Summary

510(k) SUMMARY

5.1 Type of Submission Special

5.2 Date of Summary November 8, 2019

5.3 Submitter

HIVOX BIOTEK INC.
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: Marx Lee
(Marx.Lee@hivox-biotek.com)

5.4 Identification of the Subject Device

Proprietary/Trade name:	HIVOX Spopad EMS
Models:	SP-911, SP-921
Classification product code:	NGX
Regulation number:	890.5850
Regulation description:	Power muscle stimulator
Review panel:	Physical Medicine
Device class:	II

5.5 Identification of the Predicate Device

Proprietary/Trade name:	HIVOX Spopad EMS
Models:	SP-910, SP-920
510(k) number:	K141921
Classification product code:	NGX
Regulation number:	890.5850
Regulation description:	Power muscle stimulator
Review panel:	Physical Medicine
Device class:	II

5.6 Intended Use / Indication for Use of the Device

These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

5.7 Description of the Device

EMS, Electrical Muscle Stimulator, which improves, tones, firms & strengthens muscle and relaxes stiff muscle through the skin. It is recognized as a clinically proven, effective, non-medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.

HIVOX Spopad EMS SP series, SP-911 and SP-921 are the proposed devices for the 510(k) submission. These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in therapy or for the treatment of any medical conditions or diseases.

SP-911 and SP-921 are 1-channel battery-operated-user-friendly muscle stimulation system specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-911 comprises 2 electrodes, which connects the signals from the stimulator to the skin. SP-921 comprises 4 electrodes, which connect the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, HIVOX Spopad EMS SP-911 and SP-921.

- Shelf-Life testing
- Performance verification
- Usability validation

All the test result demonstrate HIVOX Spopad EMS SP-911 and SP-921 meet the requirement of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

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

5.10 Comparison of Differences and Substantial Equivalence Determination

5.10.1 Comparison between SP-910 and SP-911

Item	Subject device	Predicate device	Substantial equivalence determination
Device name	HIVOX Spopad EMS	HIVOX Spopad EMS	N/A
Model name	SP-911	SP-910	
510(k) number	K192264	K141921	
Product code	NGX	NGX	Identical
Classification name	Powered Muscle Stimulator	Powered Muscle Stimulator	Identical
Regulation number	21 CFR 890.5850	21 CFR 890.5850	Identical
Indication for use	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	Identical
Technology	Electrical Muscle Stimulation	Electrical Muscle Stimulation	Identical
Size (L × W × H, inch)	8.15 × 4.06 ×	9.41 × 2.76 ×	Different but

	0.51	0.45	does not adversely impact safety and effectiveness of subject device
Weight (g)	24.2	35.8	Different but does not adversely impact safety and effectiveness of subject device
Power source	3 V battery × 1	3 V battery × 1	Identical
Method of Line Current Isolation	Battery supply	Battery supply	Identical
Patient Leakage Current Normal Condition (μA)	2.0	2.0	Identical
Patient Leakage Current Single Fault Condition (μA)	2.1	2.1	Identical
Method of channel isolation	Single channel	Single channel	Identical
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0	Identical
Number of output modes	1	1	Identical
Regulated current or regulated voltage?	Voltage	Voltage	Identical
Software / Firmware / Microprocessor control?	Yes	Yes	Identical
Automatic overload trip?	No	No	Identical
Automatic no-load trip?	No	No	Identical
Automatic shut-off?	Yes	Yes	Identical
User overrides control?	Yes	Yes	Identical
Indicator display – On / Off Status	No	No	Identical
Indicator display –	No	No	Identical

Low battery?			
Indicator display – Voltage / Current level	No	No	Identical
Timer range (minutes)	20	20	Identical
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Identical
Compliance with 21 CFR 898?	Yes	Yes	Identical
Housing material and construction	Silicone	Silicone	Identical
Output waveform	Symmetrical biphasic	Symmetrical biphasic	Identical
Shape	Rectangular	Rectangular	Identical
Duration of primary (depolarizing) phase	0	0	Identical
Pulse duration (μs)	400	400	Identical
Maximum output voltage (V, ±10%) at 500 Ω	52	52	Identical
Maximum output voltage (V, ±10%) at 2k Ω	102	102	Identical
Maximum output voltage (V, ±10%) at 10k Ω	150	150	Identical
Maximum output current (mA, ±10%) at 500 Ω	104	104	Identical
Maximum output current (mA, ±10%) at 2k Ω	51	51	Identical
Maximum output current (mA, ±10%) at 10k Ω	15	15	Identical
Frequency (Hz)	3/4/5	3/4/5	Identical
Net charge per pulse at 500 Ω (μC)	0.416	0.416	Identical
Maximum charge at 500 Ω (μC)	41.6	41.6	Identical
Conductive surface area (cm^2)	62.20 (Two electrodes)	87.58 (Two electrodes)	Identical
Maximum current density at 500	1.672	1.187	Different but

Ω (mA/cm^2)				does not adversely impact safety and effectiveness of subject device
Maximum average power density at 500 Ω (W/cm^2)		0.0869	0.0617	Different but does not adversely impact safety and effectiveness of subject device
Burst mode	A. Pulse per burst	N/A	N/A	Identical
	B. Burst per second	N/A	N/A	Identical
	C. Burst duration (sec)	N/A	N/A	Identical
	D. Duty cycle	N/A	N/A	Identical

5.10.2 <u>Comparison between SP-920 and SP-921</u>

Item	**Subject device**	**Predicate device**	**Substantial equivalence determination**
Device name	HIVOX Spopad EMS	HIVOX Spopad EMS	N/A
Model name	SP-921	SP-920	
510(k) number	K192264	K141921	
Product code	NGX	NGX	Identical
Classification name	Powered Muscle Stimulator	Powered Muscle Stimulator	Identical
Regulation number	21 CFR 890.5850	21 CFR 890.5850	Identical
Indication for use	Indicated for the improvement of muscle tone and firmness, for strengthening	Indicated for the improvement of muscle tone and firmness, for strengthening	Identical

	muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	
Technology	Electrical Muscle Stimulation	Electrical Muscle Stimulation	Identical
Size (L × W × H, inch)	7.17 × 6.81 × 0.51	6.69 × 6.69 × 0.51	Different but does not adversely impact safety and effectiveness of subject device
Weight (g)	48.3	52.6	Different but does not adversely impact safety and effectiveness of subject device
Power source	3 V battery × 1	3 V battery × 1	Identical
Method of Line Current Isolation	Battery supply	Battery supply	Identical
Patient Leakage Current Normal Condition (μA)	2.0	2.0	Identical
Patient Leakage Current Single Fault Condition (μA)	2.1	2.1	Identical
Method of channel isolation	Single channel	Single channel	Identical
Average DC current through	0	0	Identical

electrodes when device is on but no pulses are being applied (μA)			
Number of output modes	1	1	Identical
Regulated current or regulated voltage?	Voltage	Voltage	Identical
Software / Firmware / Microprocessor control?	Yes	Yes	Identical
Automatic overload trip?	No	No	Identical
Automatic no-load trip?	No	No	Identical
Automatic shut-off?	Yes	Yes	Identical
User overrides control?	Yes	Yes	Identical
Indicator display – On / Off Status	No	No	Identical
Indicator display – Low battery?	No	No	Identical
Indicator display – Voltage / Current level	No	No	Identical
Timer range (minutes)	20	20	Identical
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Identical
Compliance with 21 CFR 898?	Yes	Yes	Identical
Housing material and construction	Silicone	Silicone	Identical
Output waveform	Symmetrical biphasic	Symmetrical biphasic	Identical
Shape	Rectangular	Rectangular	Identical
Duration of primary (depolarizing) phase	0	0	Identical
Pulse duration (μs)	400	400	Identical
Maximum output voltage (V, ±10%) at 500 Ω	58.4	58.4	Identical
Maximum output voltage (V, ±10%) at 2k Ω	106	106	Identical
Maximum output voltage	154	154	Identical

(V, ±10%) at 10k Ω				
Maximum output current (mA, ±10%) at 500 Ω		117	117	Identical
Maximum output current (mA, ±10%) at 2k Ω		53	53	Identical
Maximum output current (mA, ±10%) at 10k Ω		15.4	15.4	Identical
Frequency (Hz)		2/4/25	2/4/25	Identical
Net charge per pulse at 500 Ω (μC)		0.468	0.468	Identical
Maximum charge at 500 Ω (μC)		46.8	46.8	Identical
Conductive surface area (cm^2)		110.68 (four electrodes)	110.68 (four electrodes)	Identical
Maximum current density at 500 Ω (mA/cm^2)		1.057	1.057	Identical
Maximum average power density at 500 Ω (W/cm^2)		0.0617	0.0617	Identical
Burst mode	E. Pulse per burst	25	25	Identical
	F. Burst per second	1	1	Identical
	G. Burst duration (sec)	20	20	Identical
	H. Duty cycle	20	20	Identical

The HIVOX Spopad EMS SP-911 and SP-921 submitted in this 510(k) file are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared HIVOX Spopad EMS SP-910 and SP-920 (K141921) respectively. Differences between the devices cited in the following do not raise any new issue of substantially equivalence.

(1) Comparison of SP-910 and SP-911:

Feature	Substantial equivalence justification
Labeling	Different in product model. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Appearance	Changed for the sake of product segmentation. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.

Conductive surface area	Compared with predicate device (SP-910), the calculated power density value of the subject device (SP-911) is raised from 0.0617 W/cm^2 to 0.0869 W/cm^2 due to the smaller size of gel pad. However, we believe that the product safety will not be affected because the power density is still far below than the acceptance criterion (0.25 W/cm^2) based on the recommendation of *Class II Special Control Guidance Document: Powered Muscle Stimulator for Rehabilitation* issued on April 5, 2010. Certainly, the intended use and the fundamental scientific technology of subject device will not be affected and altered by this difference.
Weight	Difference because of different design of product appearance. However, it does not affect the intended use or later the fundamental scientific technology of subject device.

(2) Comparison of SP-920 and SP-921:

Feature	Substantial equivalence justification
Labeling	Different in product model. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Appearance	Changed for the sake of product segmentation. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Weight	Difference because of different design of product appearance. However, it does not affect the intended use or later the fundamental scientific technology of subject device.

5.11 <u>Discussion</u>

The HIVOX Spopad EMS SP-911 and SP-921 have been compared with HIVOX Spopad EMS SP-910 and SP-920 respectively. The subject devices have the same intended use, principle of operation and technological characters as the predicate device. We have completed the design control process and the validation tests to confirm the safety and performance of subject device. Although there are some specifications that are different between the subject devices and

predicate devices, the test results complied with the test requests, and this demonstrates that the differences between these parameters would not impact the safety and effectiveness of the subject device. Therefore, the difference between the subject devices and predicate devices did not raise any problem of substantial equivalence. The subject devices are substantially equivalent to the predicate devices intended use, safety and performance claims.

5.12 Conclusion

After analyzing non-clinical studies and related testing data, it can be concluded that the HIVOX Spopad EMS SP-911 and SP-921 are substantially equivalent to the predicated devices.