HIVOX

HIVOX BIOTEK INC.
5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan
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SUMMARY OF SAFETY AND EFFECTIVENESS
for HIVOX Electric Stimulator OTC TENS

MAR 19 2012

510(k) : **K112392**

DATE OF SUBMISSION:	July 13, 2011
SUBMITTER:	HIVOX BIOTEK INC. 5F, No.123, Shinde Road, Sanchong Dist., New Taipei City, 24158, TAIWAN, R.O.C. TEL: 886-2-85112668 FAX:886-2-85112669
ESTABLISHMENT REGISTRATION NO:	9611558
OFFICIAL CONTACT:	Dr. JEN, KE-MIN TEL: 886-2-85112668 FAX:886-3-5209783 Email: ceirs.jen@msa.hinet.net
TRADE NAME:	HIVOX Electric Stimulator OTC TENS Pennypad 904 and Pennypad 909 : OTC TENS – Lower Back pain relieve Pennypad 907: OTC TENS – Arm and Leg pain relief
COMMON/USUAL NAME:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
CLASSIFICATION NAME:	Transcutaneous Nerve Stimulator
REGULATION NUMBER:	NUH, Class II, 882.5890
SECONDARY PRODUCT CODE:	GZJ, Class II, 882.5890
PREDICATED DEVICE:	Therapeutic Massage Companion, Endurance Therapeutics 1) K060846, OTC TENS for Lower Back, Arm and Leg Pain Relief, T1040 WELL-LIFE Healthcare Limited 2) K040512, Limited Function OTC TENS, for Lower Back Pain Relief, WL-2402, WL-2403

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Intended Use:

The HIVOX Electric Stimulator OTC TENS, Pennypad 904 and Pennypad 909 are indicated for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

The HIVOX Electric Stimulator OTC TENS, Pennypad 907 is indicated for Arm & Leg Pain Relief is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Description of Device:

The HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909 can generate small pulses of electrical current. Delivered these pulses pass through the skin and activated underlying nerves.

Performance Tests Submitted:

The relevant standards including:

1. IEC/EN 60601-1 : Medical electrical equipment Part 1. General requirements for safety, 1996.
2. IEC/EN 60601-1-2 : Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2007.
3. IEC/EN 60601-2-10 : Medical electrical equipment, Part 2-10: Particular requirements for safety of nerve and muscle stimulators, 2001.

Non-Clinical Tests Submitted:

The HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909 have been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety of nerve stimulators.

Accessories also meet safety requirements: 510(k) electrodes are specified the safety requirements.

System level testing including waveform testing was performed in combination the HIVOX Electric Stimulator OTC TENS.

Clinical Tests Submitted:

None

Conclusion:

As the product description and tests as above, the new devices: HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909 are as safe and effective as, and the function in a manner equivalent to the predicate devices: K060846, OTC TENS for Lower Back, Arm and Leg Pain Relief, T1040; and K040512, Limited Function OTC TENS, for Lower Back Pain Relief, WL-2402, WL-2403.

Thus the new device is substantially equivalent to the predicate devices in this aspect.

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Comparison for Predicate Device & Subject Device

- COMPARISON TABLE 1

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

Parameter			HIVOX		Well Life (K)040512	Endurance Therapeutics (K)060846
Mode or Program Name			PP909	PP904	2402/2403	T1040
Waveform			Symmetrical Biphasic		Biphasic	Biphasic
Shape			Rectangular		Rectangular	Rectangular
Maximum Output Voltage (Volts) (±20%)		@500Ω	40.0Vpp	57.6Vpp	38.2V rms	40.7V
		@2KΩ	84.0Vpp	89.6Vpp	52.8V rms	105.1V
		@10KΩ	92.0Vpp	96.0Vpp	84.8V rms	154.1V
Maximum Output Current(±20%)		@500Ω	80.0mApp	115.2mApp	76.2mA rms	81.4mA
		@2KΩ	42.0mApp	44.8mApp	52.8mA rms	47.8mA
		@10KΩ	9.2mApp	9.6mApp	8.48mA rms	15.4mA
Duration of primary (depolarizing) phase (μSec)			NA		NA	NA
Pulse Duration (μSec)			200μSec (fixed)		250μSec	4.1~500mS
Frequency (Hz)			35	2, 5, and 40	25Hz	245Hz
Net Charge (μC) per pulse		@500Ω	0.3200	0.2304	16.0/8.76	4.07
Maximum Charge (μC)		@500Ω	16.0	23.04	12.5/9.2	16.9
Maximum Current Density (mA/cm^2, r.m.s.)		@500Ω	1.964	2.828	0.006	2.71
Maximum Average Power Density (W/cm^2)		@500Ω	0.078	0.163	0.000848/ 0.002292	5.35 (mW/cm^2)
Burst Mode	a. Pulse per burst		1	NA	NA	NA
	b. Burst per second		4	NA	NA	NA
	c. Burst duration (sec)		2	NA	NA	NA
	d. Duty Cycle		8	NA	NA	NA
ON Time(sec)			120		NA	NA
Off Time(sec)			0		NA	NA
Additional Features			NA		NA	NA

Note: The subject device only Pennypad 909 has the "Burst Mode".

Formula

Current Density – ((Max Voltage@500ohm)x1000)/electrode area ($40.732cm^2$)

Power Density – (Amp x V)/ Electrode Area($40.732cm^2$)

- COMPARISON TABLE 2

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

Parameter			HIVOX	Endurance Therapeutics (K)060846
Mode or Program Name			PP907	T1040
Waveform			Symmetrical Biphasic	Biphasic
Shape			Rectangular	Rectangular
Maximum Output Voltage (Volts) (±20%) Peak to peak		@500Ω	68.8V	40.7V rms
		@2KΩ	88.0V	105.1V rms
		@10KΩ	95.2V	154.1V rms
Maximum Output Current(±20%) Peak to peak		@500Ω	137.6mA	81.4mA rms
		@2KΩ	44.0mA	47.8mA rms
		@10KΩ	9.52mA	15.4mArms
Duration of primary (depolarizing) phase (μSec)			NA	NA
Pulse Duration (μSec)			200μSec (fixed)	4.1~500mS
Frequency (Hz)			2 and 40	245Hz
Net Charge (μC) per pulse		@500Ω	1.1008	4.07
Maximum Charge (μC)		@500Ω	27.52	16.9
Maximum Current Density (mA/cm^2, r.m.s.)		@500Ω	3.378	2.71
Maximum Average Power Density (W/cm^2)		@500Ω	0.232	5.35 (mW/cm^2)
Burst Mode	a. Pulse per burst		NA	NA
	b. Burst per second		NA	NA
	c. Burst duration (sec)		NA	NA
	d. Duty Cycle		NA	NA
ON Time(sec)			120	NA
Off Time(sec)			0	NA
Additional Features			NA	NA

Formula:

Current Density – ((Max Voltage@500ohm)x1000)/electrode area (40.732cm^2)

Power Density – (Amp x V)/ Electrode Area(40.732cm^2)

DISCUSSION:

The HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909 have the same visional appearance, software, and dimensions (113 * 70 * 9.7 mm) the main difference is:

- Pennypad 904 and Pennypad 909 : OTC TENS – Lower Back pain relieve
- Pennypad 907: OTC TENS – Arm and Leg pain relief
- Only Pennypad 909 has the "Burst Mode".

As the product description and tests as above, the new devices: HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909 are as safe and effective as, and the function in a manner equivalent to the predicate devices: K060846, **OTC** TENS for Lower Back, Arm and Leg Pain Relief, T1040; and K040512, Limited Function **OTC** TENS, for Lower Back Pain Relief, WL-2402, WL-2403.. Thus the new devices are substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

HIVOX BIOTEK, Inc.
c/o Dr. Ke-Min Jen
Official Correspondent
5F., No. 123, Shinde Road
Sanchong District
New Taipei City
China, Taiwan 24158

MAR 19 2012

Re: K112392
Trade/Device Name: HIVOX Electric Stimulator OTC TENS
Models: Pennypad 904, 909 – Lower back pain relief
Pennypad 907 – Arm and Leg pain relief
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: February 24, 2012
Received: March 8, 2012

Dear Dr. Jen:

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,

Kenia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K112392

Device Name: HIVOX Electric Stimulator OTC TENS
Pennypad 904, 909 : OTC TENS – Lower back pain relieve
Pennypad 907: OTC TENS – Arm and Leg pain relief

Indications for Use :

The Pennypad 904 and Pennypad 909 are indicated for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

The Pennypad 907 is indicated for Arm & Leg Pain Relief is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use _____ AND/OR Over-The-Counter Use _√_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112392