HIVOX®

HIVOX BIOTEK INC.
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JUL 2 5 2014
K131720

510(K) SUMMARY
(Per 21 CFR 807.92.)

Submission Date:	July 22, 2014
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Establishment Registration No.:	9611558
Official Contact:	Dr. Jen, Ke-Min Tel: 886-2-85112668 Fax:886-3-5209783 Email: ceirs.jen@msa.hinet.net
Common / Usual Name:	Electrode, Cutaneous
Trade Name:	HIVOX self-adhesive electrode gel pads.
510(k) Number:	K131720
Classification Code:	GXY, Class II, 882.1320
Intended Use:	HIVOX self-adhesive electrode gel pads are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself. .
Predicated Devices:	1) K070612, Top-Rank Adhesive Electrodes Top-Rank Health Care Equipment Co., Ltd. 2) K132588, Top-Rank Adhesive Electrodes Top-Rank Health Care Equipment Co., Ltd. 3) K000947, Ultrastim Electrode Axelgaard Mfg. Co., Ltd.
Device Description:	HIVOX self-adhesive electrode gel pads are series of cutaneous electrodes with various shapes and sizes, which use the same materials from the predicate suppliers, i.e. K070612 (Top-Rank Health Care Equipment Co., Ltd.) and K000947 (Axelgaard Mfg. Co., Ltd.). HIVOX self-adhesive electrode gel pads are non-sterile, self-adhesive, for single patient use only, and to be disposable.

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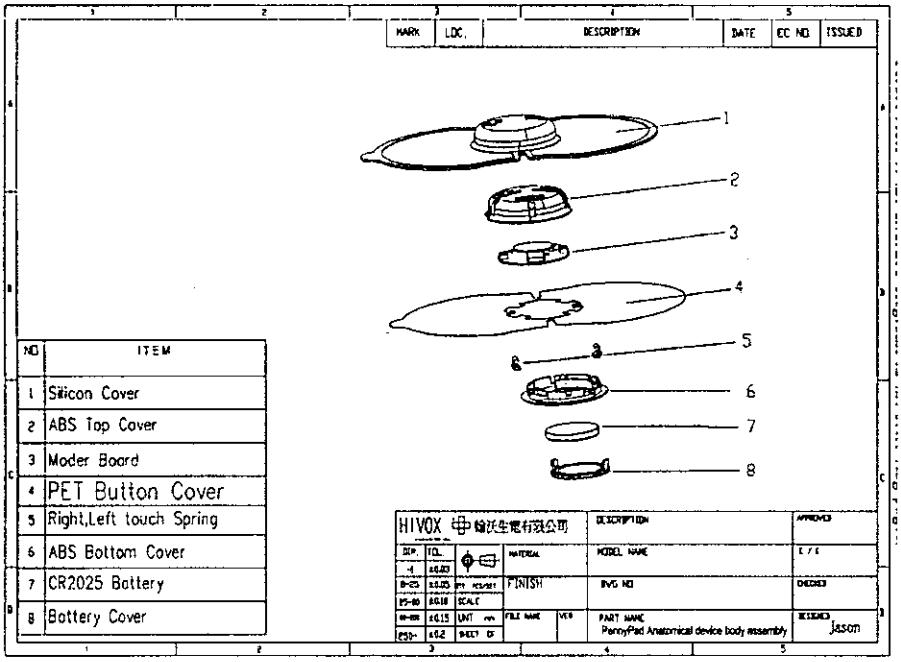
Specifications: HIVOX self-adhesive electrode gel pads have the following possible dimensions and shapes.



Scientific Concept: When we put the battery into the stimulator device, and the device will enable to transmit the electric pulse to the device's electrode area. The self-adhesive electrode gel pads should be placed onto the bottom of PET cover to enable to stick on the user's skin and conduct the electric pulse fully around the self-adhesive electrode gel pads.

Function and Characteristics:

- HIVOX self-adhesive electrode gel pads are non-sterile, self-adhesive, for single patient use only, and to be disposable.
- The subject device is designed for Hivox device use only.
- HIVOX self-adhesive electrode gel pads are series of cutaneous electrodes with various shapes and sizes, which use the same material as K070612 (Top-Rank Health Care Equipment Co., Ltd.) and K000947 (Axelgaard Mfg. Co., Ltd.).

Performance Tests: Biocompatibility Tests:

- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for in irritation and skin sensitization.

Clinical Tests: NONE

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Comparison table

Items	Predicate device	Predicate device	Predicate device	Subject Device
Trade Name	Top-Rank Adhesive Electrode	Top-Rank Adhesive Electrode	ULTRASTIM ELECTRODE, MODEL US4040	HIVOX self-adhesive electrode gel pads.
Manufacturer	Top Rank	Top Rank	Axelgaard	Top Rank, Axelgaard
510(k) Number	K070612	K132588	K000947	K131720
Intended Use	Top-Rank Adhesive Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). These electrodes will include the precaution statement: Federal Law restricts the device to sale by or on the order of a licensed practitioner or therapist.	Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).	UltraStim Electrodes are intended for use with a garment/wrap designed with a snap connection for distributing electrical impulses from transcutaneous neurostimulation devices to UltraStim electrodes placed on the skin. Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.	HIVOX Self Adhesive Electrodes are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself. .
Prescription Use	Prescription use	OTC	Prescription use	Prescription use & OTC
Classification Name	Cutaneous Electrode	Cutaneous Electrode	Cutaneous Electrode	Cutaneous Electrode

Product Code	GXY 882.1320	GXY 882.1320	GXY 882.1320	GXY 882.1320
Single-Patient Use	Yes	Yes	Yes	Yes
Multiple Applications	Yes	Yes	Yes	Yes
Sterility Status	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Biocompatibility Test	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10
Conductive Surface Shapes	Various shapes (rectangular, circle, oval)	Various shapes (rectangular, circle, oval)	Various shapes (rectangular, circle, oval)	Various shapes (rectangular, circle, oval)

Predicated Technological Characteristics Comparison:

The subject device, HIVOX self-adhesive electrode gel pads, uses the same materials from the suppliers, predicate devices' manufacturers. And the suppliers, Top Rank and Axelgaard will provide all components materials of the HIVOX self-adhesive electrode gel pads.

The differences between the subject device and K000947 are prescription use and OTC use. The subject device has OTC use but K000947 hasn't OTC use. But we have added a predicate device K132588 with OTC use, the OTC use of the safety and effectiveness of our device are ensured.
The subject device and predicate device (K000947) have the minor different intended use and use the same gel ingredients and the conductive films; thus the effects of impedance levels for the intended situations are the same for both of the devices. We notice there are different wording of the intended uses between the subject device and the predicate device K000947. But the key sentences for K000947 : serving as an interface between a patient's skin and a neurostimulation device, and the key sentences for the subject device : interface between the patient's skin and the electrical stimulator are similar. Thus they have similar intended use. Both of them have the same safety and effectiveness.

And all of four devices had passed the Tripartite Biocompatibility Guidance for Medical Devices and the ISO 10993 relevant requirements for skin contact. Thus the subject device and predicate devices have the same safety and effectiveness.

The subject device and the predicate devices have the same physical and technological characteristics, which are intended to be used with marketed Electrical Stimulators, including: TENS(Transcutaneous Electrical Nerve Stimulator), EMS (Electrical Muscular Stimulator), and IF (Interferential Stimulator). And all of the devices are for gel pads use with an electrode and not an electrode itself.

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 25, 2014

HIVOX BIOTEK, Inc.
Dr. Jen, Ke-Min
5 F No. 123 Shinde Road
Sanchong District
New Taipei City 24158
TAIWAN, ROC

Re: K131720
Trade/Device Name: HIVOX Self-Adhesive Electrode Gel Pads
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrodes
Regulatory Class: Class II
Product Code: GXY, GYB
Dated: June 18, 2014
Received: June 25, 2014

Dear Dr. Jen, Ke-Min,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Felipe Aguel -S

for Carlos Pena, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131720

Device Name
HIVOX Self-Adhesive Electrode Gel Pads

Indications for Use *(Describe)*
HIVOX self-adhesive electrode gel pads are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.07.25 17:34:13 -04'00'

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