K132563

APR 2 4 2014

Summary
Traditional 510(K)

SUBMITTER INFORMATION

Submitter's Name:	Pinook USA
Submitter's Address:	901 Central Florida Pkwy Suite A6 Orlando, Florida 32824
Contact Person:	Mr. Dvir Lev-Ran
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Date of Summary Submission:	July 29, 2013
Resubmitting on:	March 24th, 2014
510(K) Number:	K132563

NEW DEVICE FOR WHICH SUBMITTING:

Device Trade Name:	Pinook Stimulator
Model:	**BH-18**
Device Common Name:	**Transcutaneous Electrical Nerve Stimulator and Powere Muscle Stimulator**
Classification Name:	**Stimulator, Nerve, Transcutaneous, Over-the-Counter** **Stimulator, Muscle, Powered, For Muscle Conditioning**
Device's Classification Panel:	**Neurology** **Physical Medicine**
Regulatory Class:	**Class II**
Product Code: Regulation Number:	**NUH, NGX** **882.5890**

MANUFACTURER INFORMATION:

Name:	**JOHARI DIGITAL HEALTHCARE LTD.**
Address and Registration:	**G-582 - 583, EPIP, Boranada, Jodhpur 342008**
FDA Registration:	**8040537**

Predicate Device:

Device Trade Name:	**Hi-Dow**
Model:	**JQ-5C**
Classification Name:	**Stimulator, Nerve, Transcutaneous, Over-the-Counter** **Stimulator, Muscle, Powered, For Muscle Conditioning**
510(K) Number:	**K102598**
Device's Classification Panel:	**Neurology (As Per 21 CFR Section 882.5890)** **Physical Medicine (As Per 21 CFR Sections 890.5850)**
Regulatory Class:	**Class II**
Product Code:	**NUH, NGX**
Regulation Number:	**882.5890**
Manufacturer:	**Hi-Dow International, Inc**
Address:	**2071 Congressional Drive, Saint Louis, MO 61346**

DESCRIPTION OF THE NEW DEVICE

BH - 18:

The BH - 18 is a portable; battery powered (3.7VDC) multi-function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device.

Two channels effectively transfer your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, there are 6 modes of operation.

INTENDED USE OF DEVICE

TENS:

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.

PMS:

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Comparison of BH - 18 and the predicate JQ-5C.

S.No	Description	Pinook Stimulator	Hi-Dow
1.	Max Output Voltage over 10k, V	84 V @ 10KΩ 79 V @ 2.2KΩ 61 V @ 500Ω	84 V @ 10KΩ 79.2 V @ 2.2KΩ 62.4 V @ 500Ω
2.	Max- Current over l0k, mA	8.4 mA @ 10KΩ 39.5 mA @ 2.2KΩ 122 mA @ 500Ω	8.4 mA @ 10KΩ 39.6 mA @ 2.2KΩ 124.8 mA @ 500Ω
3.	Pulse Width, micro seconds	100	100
4.	Pulse Period, msec	16.3-833Ms	16.3-833mS
5.	Max. Pulse Frequency, Hz	62	61.3
6.	Net Charge μC per pulse	0	0
7.	Max Phase Charge over 500Ω, μC	12.2	12.48
8.	Max Current Density over 500Ω, mA/cm2	11.77	12.04
9.	Max Power Density over 500 Ω, W/cm^2	0.718 W/cm^2	0.747 W/cm^2
10.	For multiphasic waveforms only: -Symmetrical phases? - Phase Duration† (include units)	 YES 100μS	 YES 100μS
11.	ON Time (seconds)	5 Seconds (M2, M3 & M4)	5 Seconds (M2, M3 & M4)
12.	OFF Time (seconds)	3 Sec. (M2), 2 Sec. (M3 & M4)	3 Sec. (M2), 2 Sec. (M3 & M4)

SUBSTANTIAL EQUIVALENCE

The electrical stimulation provided by the BH-18 is substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for

marketing without prescription labelling; i.e. for OTC sale. The pulses in the waveform combinations are restricted in amplitude and duration and is consistent with the other device quoted above.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

The BH -18 has modes that offer substantially equivalent technical specifications, features and effective results as the predicate listed.

NON-CLINICAL TESTING PERFORMED

Compliance to applicable voluntary standards includes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11 and ISO 14971.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA guidance for the content of premarket submissions for software contained in medical devices.

CONCLUSION

The electrical stimulation provided by the BH-18 is similar to the commonly employed muscle stimulators and TENS devices that have been cleared for marketing without prescription labelling.

The BH-18 has the same intended uses and the similar technological characteristics as its OTC predicate. Moreover, verification and validation tests contained in this submission demonstrate that the differences in BH-18 still maintain the same safety and effectiveness as that of the cleared device.

In other words, the engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Concerns of safe and proper use of electrodes and electrode pad placement have been fully addressed by making the user conscious of the proper placement of the electrodes and proper operations of the device through detail in the User's Instruction Manual.

There are no new safety or effectiveness issues concerning the new device.

The safety of the device, to be used for the proposed indications without medical prescriptions or supervision, is established by the fact that no adverse events have been reported for units sold without a prescription in Europe and Asia. This also proves that its specific technical, safety measures and features are safe and effective when used without medical supervision.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrates that electrical stimulation does improve muscle performance as well as pain reduction.
Technological characteristics, features, specifications, materials and intended uses of the BH-18 are substantially equivalent to the quoted predicate device.

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

April 24, 2014

Pinook USA, LLC
c/o Dvir Lev-Ran
901 Central Florida Parkway, Suite A6
Orlando, FL 32824

Re: K132563
Trade/Device Name: Pinook Stimulator, Model BH-18
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: March 24, 2014
Received: March 27, 2014

Dear Mr. Lev-Ran:

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 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. 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,

Carlos L. Peña-S

Carlos L. Peña, Ph.D., M.S.
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 on last page.

510(k) Number *(if known)*
K132563

Device Name
Pinook Stimulator, Model BH-18

Indications for Use *(Describe)*
TENS: 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

PMS: To be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

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)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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