DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

Biegler Gmbh
% Paul Dryden
Consultant
Promedic, Inc.
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K152571
Trade/Device Name: Stivax System
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: BWK
Dated: April 24, 2016
Received: April 26, 2016

Dear Paul Dryden,

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" (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.

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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.05.26 11:24:18 -04'00'

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: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*

K152571

Device Name

Stivax System

Indications for Use *(Describe)*

Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Type of Use *(Select one or both, as applicable)*

[X] 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)*

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**Official Contact:** Friedrich Netauschek
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Allhangstrasse 18a
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Tel - (0043)1979210515
Fax - (0043)1979210516

**Proprietary or Trade Name:** Stivax System

**Common/Usual Name:** Electro-acupuncture devic

**Classification Name:** Not classified (pre-amendment)

**Predicate Device:** Biegler P-Stim System - K140788

**Device:** Stivax System

**Device Description:**
The Stivax is a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve via the ear. The device connects an electrode cable to two sterile (radiation) acupuncture needles that have been applied by a healthcare practitioner. The stimulator connects to a clip holder on medical grade adhesive tape. The stimulator (with tape) adheres to the patient, behind the ear.

The STIVAX and the sterile (radiation) stimulation double needle are intended for single use.

The device consists of the stimulator and a stimulation double needle. The device cannot be recharged. The device has no connection to any external devices except the electrode.

The stimulator is housed in plastic. It is connected through a plug to the stimulation double needle (needles made of titanium, insulated wire). The power is supplied by a 3 V battery (type CR1220).

The dimensions of the device are W x H x D 34 x 7 x 20 mm, the weight is 4.41 g with battery.

The device is activated by connecting the stimulation double needle.

**Intended User**
Clinician

**Patient Population**
This device is intended for use on adults.

**Indications for Use:**
Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

**Environment of Use:**
Clinics, hospital and home environments

**Contraindications:**

- Use of cardiac pacemakers because no clinical data are available
- Hemophilia
- Psoriasis vulgaris

**Predicate Device Comparison:**

The Stivax System from Biegler was compared to the predicate P-Stim System - K140788 in the device comparison table below.

**Device Comparison**

| | **STIVAX** | **Predicate P-STIM K140788** |
|---|---|---|
| Manufacturer | Biegler GmbH | Biegler GmbH |
| Power source | 3 V battery (CR1220) | 3x 1.4 V- zinc air batteries |
| Line Current Isolation | NA - Internally powered only. No connection to mains or any other equipment | NA - Internally powered only. No connection to mains or any other equipment |
| Indications for Use | Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states | P-STIM is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states |
| Patient Population | Adults | Adults |
| Environment of use | Clinics, hospital and home environments | Clinics, hospital and home environments |
| Contraindications – | • Use of cardiac pacemakers because no clinical data are available<br>• Hemophilia<br>• Psoriasis vulgaris | • Use of cardiac pacemakers because no clinical data are available<br>• Hemophilia<br>• Psoriasis vulgaris |
| Number of Output modes | 1 | 1 |
| Number of Output channels | 1 | 1 |
| Waveform | Monophasic | Biphasic |
| Waveform Shape | Rectangular | Rectangular |

| | **STIVAX** | **Predicate P-STIM K140788** |
|---|---|---|
| Maximum Output Voltage (max)<br>- 500 Ω<br>- 1000 Ω<br>- 2 kΩ<br>- 10 kΩ | <br>0.56 V<br>1.09 V<br>2.05 V<br>8.40 V | <br>2.74 V<br>3.31 V<br>3.56 V<br>3.75 V |
| Maximum Output Current (max)<br>- 500 Ω<br>- 1000 Ω<br>- 2 kΩ<br>- 10 kΩ | <br>1.12 mA<br>1.09 mA<br>1.025 mA<br>0.84 mA | <br>5.52 mA<br>3.31 mA<br>1.75 mA<br>0.38 mA |
| Maximum Phase charge (500 Ω) | 0.224 µC | 3.31 µC |
| Contact Area (needle electrode) | 3.796 mm²<br>(2 needles x 1.898 mm²) | 1.898 mm²<br>(1 needle) |
| Maximum Current Density (500 Ω) | 0.59 mA/mm² | 0.97 mA/mm² |
| Pulse Duration | 200 µs | 1 ms |
| Maximum Average Current (500 Ω) | 1.12 mA | 5.52 mA |
| Maximum Power Density (500 Ω) | 0.33*10-3 W/mm² | 2.66 10-3 W/mm² |
| Frequency (Hz) | 1 Hz | 1 Hz |
| Burst Mode | None | None |
| Timer range (min) | Fixed 40 min on / 20 min off | Fixed 3 h on / 3 h off |
| Indication display<br>- On/Off status<br>- Low battery<br>- Voltage / Current level<br>- Output mode<br>- Time to cut-off | <br>No<br>No<br>No<br>No<br>No | <br>No<br>No<br>No<br>No<br>No |
| Dimensions | 34 x 7 x 20 mm | 63 x 28 x 8 mm |
| Weight | 4.41 g | 5 g |
| Microprocessor control | Yes | Yes |
| Electrode cable | Yes | Yes |

**Differences Between Other Legally Marketed Predicate Devices:**
There are some differences between the subject device and the predicate P-Stim (K140788). They are:

- Difference in electrode configuration
    - P-STIM has the pad as the ground the 3 needles are connected to the same stimulation signal, effectively also acting as 2 electrodes. Whereas the STIVAX also has 2 electrodes, a ground and stimulator.
- Waveform shape

  - Biphasic stimulation is used for the predicate P-STIM because of the electrode configuration.
- Maximum Output Current
  - The constant current stimulation of the Stivax allows us to use a lower maximum output current.
- Maximum Pulse Duration
  - A pulse duration of 200 µs is enough to deliver the energy.
- Treatment protocol
  - User feedback suggested that the shorter pause of 20 min is less disruptive to the user when they are sleeping.

These differences were found to not raise any new safety or risks and thus the Biegler Stivax System can be viewed as substantially equivalent to the predicate device.

**Indications –**
Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Discussion – These indications are identical to the predicate

**Prescriptive** – The Stivax and predicate are prescriptive devices.

**Performance and Specifications** – The Stivax has equivalent specifications of performance when compared to the predicate.

**Compliance with standards –**The Stivax System and predicate comply with AAMI ANSI ES6060-1 and IEC 60601-1-2. Additionally Stivax complies with IEC 60601-2-10 for electrical stimulators.

**Materials –**
Materials inclusive of patient contacting materials of the Stivax system are similar to the predicate. The patient contact needles are of identical titanium allow. A similar medical tape is used to affix the device.

**Patient Population –**
The Stivax and predicate are indicated for adults

**Environment of Use –**
Clinics, hospital and home environments, identical to the predicate.

**Non-Clinical Testing Summary:**
We have performed bench tests and found that the Stivax System met all requirements specifications and standards requirements. Testing includes the following:

- Verification Testing to insure the device meets its specifications
- Testing of hazard mitigations
- Testing for compliance to AAMI ANSI ES60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance with IEC 60601-2-10

**Animal Testing:**
No animal testing was performed.

**Clinical Testing Summary:**
No clinical testing was performed.

**Substantial Equivalence Conclusion:**
Biegler maintains the Stivax System is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with the same international standards