APR - 8 2011

SECTION 5 – 510(k) SUMMARY

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Submission Sponsor
Therapeutics 101, Inc. (dba Pressure Point, Inc.)
36 Green Meadow Drive
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Phone: 732-747-6049
FDA Establishment Registration #: none, they will obtain number prior to marketing device.

Date Prepared
February 21, 2011

Trade Name
Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip

Classification Name
Device, Acupressure

Regulation Number
NA

Product Code
MVV

Classification Panel
Neurology

K110563

Therapeutics 101, Inc. (dba Pressure Point, Inc.)
Traditional 510(k) Premarket Submission
Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip

Device Class
Unclassified

Predicate Device
Sea-Band, by Sea-Band UK LTD
510(k) # K033268

Indications for Use
The Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip is indicated for the relief of emetic (nausea and vomiting) symptoms associated with Post-Operative Anesthesia.

Device Description
The Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip is a single-use, disposable acupressure strip that operates by exerting pressure on the Nei-Kuan (acupuncture) or (P6) pressure point.

The Pressure Right® device has a three-quarter wrist size design (5.50" long X 1.0" wide) with an affixed hard plastic button. Its pressure stimulation effect to the P6 acupressure point provides nausea and vomiting relief for surgical patients. Pressure Right® device is intended for use by adults, 18 years and older and intended to be worn on each wrist. The Pressure Right® device also comes with a P6 locator template to accurately determine an individual's P6 pressure point.

Summary of Non-Clinical Data Submitted
The following testing has been performed to support substantial equivalence:
- Bench testing to evaluate the pressure equivalence of the Pressure Right® device compared to the marketed predicate (Sea-Band) device.
- Materials with patient contact were evaluated for biocompatibility requirements with intact skin for prolonged use.

Summary of Clinical Data Submitted
The following clinical study has been performed on the Pressure Right® device to support substantial equivalence:
- Use of disposable acupressure device as part of a multi-model antiemetic strategy for reducing postoperative nausea and vomiting. Study includes evaluation of adhesive abilities of the Pressure Right® device.

Safety and Effectiveness
By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

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It has been shown in this 510(k) submission that the differences between the Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip and the predicate device do not raise any questions regarding its safety and effectiveness. The Pressure Right® device, as designed and manufactured, is therefore determined to be substantially equivalent to the referenced predicate device.

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

Therapeutics 101, Inc. (dba Pressure Point, Inc.)
c/o Julie Powell
Vice President, Quality Assurance
Emergo Group, Inc
611 West Fifth Street
Third floor
Austin, TX 78701

APR = 8 2011

Re: K110563
Trade/Device Name: Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip
Regulatory Class: unclassified
Product Code: MVV
Dated: February 24, 2011
Received: February 28, 2011

Dear Ms. Powell:

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,

for Kesia Alexander

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

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K110563

Device Name

Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip

Indications for Use

The Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip is indicated for the relief of emetic (nausea and vomiting) symptoms associated with Post-Operative Anesthesia.

Prescription Use ____X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K110563