K080386

Exhibit 2

MAY 30 2008

510 (K) Summary

Company Name: Columbia Scientific Development, LLC
420 NW 11th Ave., Suite 617
Portland, Oregon 97209

Contact: Stephen Shulman
Phone: 734-663-0132
Fax: 734-663-1306
www.stevelshul@aol.com
Summary Date: April 9, 2008

Trade Name: Columbia 600 Electrode and Columbia 06 Leadwire

Common Name: Cutaneous electrode for muscle stimulation
Leadwire for connection of cutaneous electrode to a battery powered muscle stimulator.
Establishment Registration #:
Address of manufacturer: TBD
Device Class: Class II
Product Code: GXY
New or Modification: This notification is for a new device.
Classification Name: 21 CFR 882.1320
21 CFR 898.12

Classification Panel: Neurology
Predicate Device(s):
510(K) Number: K070807,
Product Code: GXY
Applicant: Pepin Manufacturing Inc.
Trade Name: PMI Cutaneous Electrodes

1.0 Description of Electrode/Leadwire
Single patient use cutaneous electrodes for the application of electrical stimulation are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals.

The Leadwire is attached to the electrode and is designed to be connected to a transcutaneous external muscle stimulator.

The cutaneous electrodes are single patient /multiple application use and are composed of materials commonly used in this application:

First Layer- Tricot/polyester fabric, coated with biocompatible adhesive.

Second layer- Electrically conductive Activated Carbon Mesh material.

Third layer- Biocompatible conductive Hydrogel coupling media that has been tested for biocompatibility. Test report T1262-809 NAMSA CA. Division

The electrode has one type of connection point that can be used to connect to the stimulation device (For e.g. VitalStim NMES model 5900 or 5905). The lead wire assembly is 60" with .080 inch diameter recessed female socket that is in compliance with IEC 601-1(plus amendments) and section 56.3 of 21 CFR 898.12 Performance Standard and connects to the electrode and the electrical stimulation devices.

2.0 **Indication for Use of Electrode/Leadwire**

The Columbia Scientific, Inc. cutaneous electrotherapy and recording electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals.

Example electrical stimulation current applications of these electrodes are:
a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief.
b) Electrical muscle stimulation (EMS) for neck muscle stimulation
c) Functional electrical stimulation (FES).
d) Galvanic stimulation.
e) Microcurrent electrical nerve stimulation (MENS).
f) Interferential stimulation.
g) Neuromuscular electrical stimulation (NMES).

3.0 Substantial Equivalence Comparison

The cutaneous electrotherapy electrode does not contain active electronics, software or firmware and is equivalent to the predicate device. The Columbia 600 electrodes are measured for effectiveness by monitoring the impedance level and comparing the level to previously approved devices. Result's of the impedance testing revealed that the subject device's impedance values were less than the other predicate devices impedance values.

Comparison Areas	Pepin (K070807)	"Columbia 600 Electrode &Columbia 06 Leadwire
Indications for use	The Pepin Manufacturing Inc. cutaneous electrotherapy and recording electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals.	SAME

Where used	Hospitals and Clinics	SAME
Basic features Size, adhesive, packaging	25 mm diameter, non sterile, single patient use, self adhesive, 4 electrodes in sealed pouch.	SAME
Standard met	Conformance to 21CFR 898.12 standard,	SAME

5. **Conclusion**

For the above reason's, the Columbia 600 Electrode and Columbia 06 Leadwire are considered to be as safe and effective as the predicate devices and do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Columbia Scientific Development, LLC
% Regulatory Technology Services, LLC
Mr. Mark Job
Responsible Third Party Official
1394 25th Street, Northwest
Buffalo, Minnesota 55313

MAY 30 2008

Re: K080386
Trade/Device Name: Columbia 600 Electrode and Columbia 06 Leadwire
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: May 15, 2008
Received: May 16, 2008

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Columbia 600 Electrode and Columbia 06 Leadwire

The Columbia Scientific, Inc. cutaneous electrotherapy and recording electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals.

Example electrical stimulation current applications of these electrodes are:
a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief.
b) Electrical muscle stimulation (EMS) for neck muscle stimulation
c) Functional electrical stimulation (FES).
d) Galvanic stimulation.
e) Microcurrent electrical nerve stimulation (MENS).
f) Interferential stimulation.
g) Neuromuscular electrical stimulation (NMES).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K080381