

K060846

510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92(c)

1.0 Submitter's Name and Address:

Endurance Therapeutics
122B First Street, NE
Dauphin, Manitoba Canada
R7N 1B5

Contact Name:

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Dauphin, Manitoba
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DEC 03 2007

Date Prepared: August 27, 2007

2.0 Name of Device and Classifications

Trade/Device Name: T1040:

Common Name: TENS

Regulation Number: 21 CFR 882.5890

Transcutaneous Electrical Nerve Stimulator for Pain Relief

Classification Name: Stimulator, Nerve, Transcutaneous, Over-the-Counter.

Regulatory Class: Class II

Product Code NUH, NGX, GZJ

3.0 Predicate Devices

K011880 Compex Sport	Sport Muscle Stimulator	21CFR890.5850 OTC
K033122 Prizm Medical inc.	5000Z OTC TENS	21CFR882.5890 OTC
K050174 Bio Stim Kit,	Back Pain Relief System	21CFR882.5890 OTC

4.0 Device Description:

The T1040 is a portable; battery powered (4.5 VDC) multi function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device.

Independent channel (two pads) that effectively transfers your desired choice of pre-programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. A garment belt is used to hold the electrode pads to treat the lower back muscles. There are 10 modes of operation, 6 manual and 4 automatic.

Electrical Parameter Comparisons

Table 14 – Comparison Table

Quantity	T1040	Bio-Stim	Compex	5000Z
Max. Voltage over 10k Ω , V	154.1	132	126.8/103.3	226
Max. Current over 10k Ω , mA	15.4	13.2	12.7/10.3	22.6
Max. Voltage over 2.2k Ω , V	105.1	90	167.8/153.5	218
Max. Current over 2.2k Ω , mA	47.8	41	76.3/69.8	99
Max. Voltage over 500 Ω , V	40.7	29.5	48	208
Max. Current over 500 Ω , mA	81.4	59	96.1	416
Pulse Width, μ seconds	210	30 - 225	270	100
Pulse Period, msec	4.1 - 500	9 - 12.5	125	10
Max. Pulse Frequency, Hz	245	110	118	120
Max. Charge per Phase over 500 Ω , μ C	16.9	7.6	32.3	3.4
Max. Current Density over 500 Ω , mA/cm ²	2.71	3.93	3.84	16.64
Max. Average Power Density over 500 Ω , mW/cm ²	5.35	1.1	10.2	

5.0 Intended Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

6.0 Substantial Equivalence:

The electrical stimulation provided by the T1040 is substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling; i.e., for OTC sale. The pulses in the waveform combinations are restricted in amplitude and duration to values consistent with other devices quoted above.(see Appendix 4)

Technological characteristics, features, specifications, materials and intended uses of the T1040 are substantially equivalent to the quoted predicate devices.

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

The T1040 has modes that offer substantially equivalent technical specifications, features and effective results as each of the predicates listed.

7.0 Non-Clinical Tests Performed:

Compliance to applicable voluntary standards includes AAMI NS-4 1985, as well as EN 60601-1, EN 60601-1-2, ISO 9001;2000 and ISO 13485:2003

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.

8.0 Conclusion:

The electrical stimulation provided by the T1040 is similar to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling.

The T1040 has the same intended uses and the similar technological characteristics as these OTC cleared predicates. Moreover, verification and validation tests contained in this submission demonstrate that the differences in the T1040 still maintain the same safety and effectiveness as that of the cleared devices.

In other words, those 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 placements have been fully addressed by making the user conscious of the proper placement of electrodes and proper operations of the device through detail in the User's Instruction Manual.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced.

The safety of the device, to be used for the proposed indications without medical prescription or supervision, is established by the fact that no adverse events have been reported since 2002 with over 300,000 units sold with out a prescription in 20 countries.

Over 300 000 units sold with no adverse effects reported, proves its specific technical, safety measures and features are safe and effective when used without medical supervision. An even greater and more detailed user instruction manual regarding safe operation and adhesive pad placements is proposed for the USA marketplace and consumers.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical stimulation does improve muscle performance as well as temporary pain reduction.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2007

Endurance Therapeutics
% Mr. Brad Brezden
CEO
122 B – First Street, NE
Dauphin, Manitoba, Canada
R7N 1B5

Re: K060846

Trade/Device Name: T1040
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH, NGX
Dated: August 27, 2007
Received: September 4, 2007

Dear Mr. Brezden:

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.

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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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

13.0 Statement of Indication for Use

510(k) Number (if known): K060846

Device Name: T1040

Indications for Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

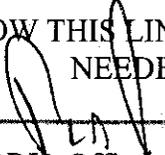
To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

Prescription Use _____ AND/OR Over-The-Counter Use XX
(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 CDREH, Office of Device Evaluation (ODE)~~
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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