K041575
510k Summary
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510(k) Summary
Fenzian Treatment System

Eumedic Limited
3 Charnham Lane
Hungerford, Berkshire RG170EY
United Kingdom
44(0)1488684008
Dominic Weiss, Director

Prepared 6-11-04 by:
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279
303-530-4774 (fax)

Device:	Fenzian Treatment System
Common Name:	Transcutaneous Electrical Nerve Stimulator
Classification	882.5890 TENS
SE Predicate:	Empi Focus 795 K951951 882.5890

Device Description: The Fenzian Treatment System is an electrical device designed for use as a Transcutaneous Electrical Nerve Stimulator (TENS) which operates by delivering an electrical current through the skin to the cutaneous (surface) and afferent (deep) nerves to control pain. The complete system is comprised of the stimulator and battery.

Indications for Use

510(k) Number (if known):

Device Name: Fenzian Treatment System

Indications For Use:

TENS applications:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post–trauma acute pain

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEDDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

COMPARISON CHART

Feature/Characteristic	Fenzian Treatment System	EMPI - Focus 795, Published Specs
510(k)	Unassigned. Application in process.	K951951
Manufacturer	Eumedic Ltd. 3 Charnham Lane Hungerford Berkshire RG170EY United Kingdom	Empi, Inc. 49 Plain Street North Attleboro, MA 02760 U.S.A.
Device Classification	Transcutaneous Nerve Stimulator (TENS) 882.5890	Transcutaneous Nerve Stimulator (TENS) 882.5890
Product Code	84 GZJ TENS	84 GZJ TENS
Indications	As a TENS device: a) Symptomatic relief and management of chronic, intractable pain b) Adjunctive treatment for post-surgical and post-trauma acute pain	As a TENS device: a) Symptomatic relief and management of chronic, intractable pain b) Adjunctive treatment for post-surgical and post-trauma acute pain
Output channels	1, alternating	2, simultaneous
Regulated voltage	Yes	Yes
Indicator display - On/Off display - Low Battery	 Yes Yes	 Yes Yes
Weight	0.4 kg excl. batteries	145 gm with battery
Dimensions	7 x 2 x 2 inches	3.7 x 2.5 x 0.84 inches
Electrodes	Stainless steel	Snapease Brand
Waveform	Biphasic	Symmetrical biphasic
Maximum Output Voltages	88 V @ 500 ohms 306 V @ 2 k ohms 650 V @ 10 k ohms	$\pm$ 100V @ 1 k ohm
Maximum Output Current	46 milliamps @ 500 ohms 16.8 milliamps @ 2 k ohms 8.0 milliamps @ 10 k ohms	 0-60 mA (normal) 0-100 mA (high)
Pulse width	498 µS	300 µS of peak amplitude
Frequency	15-350 Hz	25, 30, 35, 45, 50, 80 pps
Net Charge	1.16 µC@ 500 ohms	30 µC
Max. Phase Charge	10.6 µC @ 500 ohms	40 µC @ 500 ohm

Feature/Characteristic	Fenzian Treatment System	EMPI - Focus 795, Published Specs
Max. Current Density[2] (mA/cm^2)	27.7 mA/cm^2 @ 500 ohms	3.11 mA/cm^2 @ 500 ohms
Avg. Power Density[2] (W/cm^2)	0.177 W/cm^2 @ 500 ohms	0.187 W/cm^2 @ 500 ohms
Burst Mode - Pulses per burst - Bursts per second - Burst duration	 1-8 15-2800 1-5 seconds	Unknown
Time On	1-5 seconds	2.5 – 50 seconds
Off Time	1 second	0-50 seconds
Power Supply Voltage	9V	9V
Max. Delivered Current	< 7.0 mA	< 10 mA
Range Load of Impedance	500-1000 ohms	Unknown
Controller	Microprocessor	Microprocessor
Housing	ABS	ABS
Maximum Patient Leakage Current	<100 µA	<100 µA
Maximum Charge per Pulse	37.5 µC @ 500 ohms	Unknown
Maximum Average Current	2.19 mA	Unknown

510K Summary
K986097

Substantial Equivalence Rationale

1. The Fenzian Treatment System has the same Indications for Use and equivalent output.
2. The technological characteristics are equivalent.
3. Comparative information demonstrates substantial equivalence.

Non-Clinical Data:

1. Risk Analysis results demonstrate acceptable and mitigated potential hazards.

2. The device meets the requirements for EN 60601-1-2 EMC, Radiated Emissions, Electrostatic Discharge, Radiated Immunity and device safety.

3. The device meets European requirements for application of the CE Mark.

Conclusion:
The device is designed and labeled and verified for performance and safety. The performance is equivalent to a legally marketed predicate device. Risk Analysis does not demonstrate any design or performance potential hazards that are not adequately mitigated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Eumedic Limited
C/o Mr, Lewis W. Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K041575
Trade/Device Name: Fenzian Treatment System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: GZJ
Dated: June 11, 2004
Received: June 15, 2004

Dear Mr. Ward:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, PhD, MD
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: Fenzian Treatment System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K041573