K031546

NOV 1 3 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Number:	
Applicant Name:	Sino-Us Information, Inc.
Applicant Address:	85-13 88th Avenue Woodhaven, NY 11421
Contact Person:	Yitang Sheng
Phone:	(718)846-6868
Date Prepared:	May 5, 2003
Classification Name:	Transcutaneous Electrical Nerve Stimulator
Common/Usual Name:	TENS Unit
Trade/Proprietary Name:	Rainbow® GT-4A Pain Relief Machine (GT-4A)
Equivalent Devices:	Empi Epix XL Model 989

Product Description

The Rainbow® GT-4A is a tetrad channel traditional TENS device. It is powered by an AC adaptor. All operation modes produce the GT Bi-phasic waveform.

The GT-4A requires the use of a set of lead wires and a pair of electrodes for each channel. But no electrodes and lead wires are provided by this device. Patients must choose the products recommended by their clinician.. Selectting high quality of electrodes and lead wires is necessary for use of GT-4A and it has been observed that the quality of the electrodes may impact the ability of the GT-4A to operate efficiently, i.e. if the electrode does not adhere to the skin well the stimulative current (output) will not be delivered well.

Intended use

The Rainbow® GT-4A is indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

Comparison of Equivalent Device to the New Device

Summary of Technical Differences:

The Rainbow® GT-4A is technically identical to the Empi Epix XL Model 989, a predicate device, except that (1) an AC adaptor instead of the 9 V Alkaline Battery (or Empi rechargeable bettery), (2) only 2 and 100 Hz rates output rather than 2, 10, 20, 40, 60, 80, 100 and 150 Hz output, (3) 4 independent channels rather than 2 channels and (4) No Low Battery Indicator.

The adopted AC adaptor meets UL2601 Standards and the whole GT-4A device meets it too, i.e. it is of safety electrically. In addition, some predicate devices, e.g. Arista SD Plus TENS (K970429), are powered by an AC Adaptor too.

So this difference does not raise new questions of safety and effectiveness, and the GT-4A is as safe and as effective as the legally marketed device.

The differences in (2), (3) and (4) are not really differences in technological characteristics since underlying technology is the same as equivalent device.

Those differences do not require testing to establish equivalence.

Summary of Performance-Nonclinical

The GT-4A machine performs identically to the Epix XL 989. No clinical testing is needed.

Product Verification and Validation

The functional testing was performed and the results analyzed against product specifications demonstrates that the product meets requirements and is acceptable for its intended use.

Conclusions

This 510(k) premarket notification has demonstrated Substantial Equivalence as defined and understood in the FD&C Act and various guidance documents issued by CDRH.

Comparison of Product Specifications

See the following chart for details on the similarities and differences of the predicate device and GT-4A.

(See next pages)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Yitang Sheng,
President
Sino-U.S. Information, Inc.
85-13 88th Avenue
Woodhaven, New York 11421

Re: K031546
Trade/Device Name: Rainbow GT-4A Pain Relief Machine
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: October 15, 2003
Received: October 20, 2003

Dear Mr. Sheng:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K031546

Device Name: Rainbow® GT-4A

Indications For Use:

The Rainbow® GT-4A machine is indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

Concurrence of CDRH, Office of Device Eveluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031546

(OptionalFormat 3-10-98)