Attachment D

K021794

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

JAN 1 3 2003

Submitter's Name: Tatung Co.
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Contact: Mr.Ming-Guo Her/General Manager of Taipei Headquarter Plant

2. Device Name

Trade Name:	**TATUNG TMD-26AX Series TENS , Including** **Model No. TMD-26AB TATUNG TENS(Blue Case)** **Model No. TMD-26AY TATUNG TENS(Yellow Case)** **Model No. TMD-26AW TATUNG TENS(White Case)** **& any other case color**
Common Name:	TENS unit
Classification name:	Transcutaneous Electrical Nerve Stimulator

3. Classification: Class II

4. Predicate Device: **STIMATE TENS (K003487)** marketed by EVERYWAY MEDICAL INSTRUMENTS CO., LTD.

5. Device Description: **TATUNG TMD-26AX SERIES TENS** Transcuntaneus Electrical Nerve Stimulation System, designed for symptomatic relief and management of chronic intractable pain. It provides a combination of four stimulant modes and good for muscular pain. The device has five pre-programmed function mode, and adjustable output intensity and stimulating rate.
With large LCD panel. It is powered by three(3) AAA 1.5V Battery.
TATUNG TMD-26AX SERIES TENS requires the use of a set of lead-wire and one pair of cutaneous stimulation electrodes.

6. Intended Use: The **TATUNG TMD-26AX SERIES TENS** is intended for symptomatic relief and management of chronic intractable pain.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included EN 60601-1, EN 60601-1-2 & related FDA Output waveform requirements.

8. Conclusions:

The **TATUNG TMD-26AX SERIES TENS** have the same intended use and similar technological characteristics as the **STIMATE TENS (K003487)** marketed by EVERYWAY MEDICAL INSTRUMENTS CO., LTD. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **TATUNG TMD-26AX SERIES TENS** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2003

Tatung Corporation
C/o Ms. Jennifer Reich
Harvest Consulting, Incorporated
3892 South America West Trail
Flagstaff, AZ 86001

Re: K021794
Trade Name: TATUNG TMD-26AX Series TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: October 9, 2002
Received: October 10, 2002

Dear Ms. Reich:

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 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 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

0 (k) NUMBER (IF KNOWN): K021794

DEVICE NAME: **TATUNG TMD-26AX Series TENS**
TATUNG CO.

INDICATIONS FOR USE:

The **TATUNG TMD-26AX SERIES TENS** is intended for symptomatic relief and management of chronic intractable pain.

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K021794

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)