K100441

SECTION 5.0
S1

International Trade Group, Incorporated
4663 Katie Lane
Oxford, OH 45056
USA
Tel: 614-568-7000

JUL 15 2010

510(k) Summary

1. **General Information**

Trade Name of Device:	**"XINIXWAVE"**
Common/Usual Name:	Transcutaneous Nerve Stimulator combined with Neuromuscular Stimulator
Classification Group:	NGX, NUH
Classification Name:	Stimulator, Nerve, Transcutaneous or Pain Relief, Over-the-Counter Combined with Powered Muscle Stimulator, Over-the-Counter.
Classification regulation:	21CFR 882.5890 OTC & 890.5850 OTC
Submitter's Name: **Submitter's Address:**	International Trade Group, Incorporated 4663 Katie Lane Oxford, OH 45056 USA
Manufacturer's Name: **Manufacturer's Address:**	Mantra International (HK) Ltd. 1504 Vigor Industrial Bldg. Block B, 14-20 Cheung Tat Road Tsing Yi, Hong Kong, China
Manufacturer's FDA Reg. No:	3003741750

2. **Device Description**
The "**XINIXWAVE**" is a portable combined TENS and NMS dual channel device for OTC use. Housed in sturdy but lightweight cabinet, the device is battery powered. The same circuitry is used to for both TENS and NMS.

3. **Indications for Use**
A. TENS: The device is intended to be used for the temporary relief of pain associated with sore and aching muscles in the lower back, upper extremities (arms) and lower extremities (legs) due to strain from exercise and/or normal non-commercial household work activities.

B. NMS: The device is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

4. Substantial Equivalence

This product is substantially equivalent to the Endurance Therapeutics' T-1040 (K-060846). The device comes with a garment belt that is used to hold the electrode pads to treat the lower back muscles as does the predicate device. The device offers the user a choice of programs for both TENS and NMS as does the predicate device. The user can select either TENS or NMS modalities. In this way it is simply "two products in one" as is the cited predicate device.

5. Performance Studies

Performance testing was conducted on the "XINIXWAVE" combined TENS & NMS device to demonstrate the integrity, suitability and substantial equivalence of the device.

6. Conclusion

Based upon the Indications for use and performance studies the "XINIXWAVE" is shown to be substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

International Trade Group, Inc.
c/o Mr. Brent Reider
President
4663 Katie Lane
Oxford, Ohio 45056

JUL 16 2010

Re: K100441
Trade/Device Name: Xiniwave, Model XW-18
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NUH
Dated: June 3, 2010
Received: June 17, 2010

Dear Mr. Reider:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100441

Device Name: **XINIWAVE** (Combined TENS & NMS device)

Indications For Use:

A. TENS: The device is intended to be used for the temporary relief of pain associated with sore and aching muscles in the lower back, upper extremities (arms) and lower extremities (legs) due to strain from and/ or normal non-commercial household work activities.

B. NMS: The device is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

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

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

Daniel Kaufman

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K100441