SECTION 5.0

K083704

JUL 14 2009

Verity Scientific Ltd,
Unit 2A, Chilbolton Down Farm
Stockbridge
SO20 6BU Hampshire
England
UK
Tel: +44 (0)1264 810 102

510(k) Summary

1. **General Information**

Trade Name of Device:	**'NuTrac™ Pelvator'**
Common/Usual Name:	Pelvic muscle trainer
Classification Name:	Non-implanted electrical continence device
Submitters Name and Address:	Verity Scientific Ltd, Unit 2A, Chilbolton Down Farm Stockbridge SO20 6BU, Hampshire England UK Tel: +44 (0)1264 810 102
Manufacturer:	Mantra International (HK) Ltd. 1504 Vigor Industrial bldg Block B, 14-20 Cheung Tat Road Tsing Yi, Hong Kong, China **Registration Number**: 3003741750

2. **Device Description**

The **'NuTrac™ Pelvator'** Pelvic Muscle Trainer is a small lightweight battery powered dual channel neuromuscular stimulation device supplied with a vaginal two electrode stimulation probe
The probe connects to the control unit by cable and plug
The **'NuTrac™ Pelvator'** is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women

3. **Indications for Use**

The **'NuTrac™ Pelvator'** Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women

4. **Substantial Equivalence**

The **'NuTrac™ Pelvator'** Pelvic Muscle Trainer is substantially equivalent to: the "Kegel8" Pelvic Muscle Trainer (K0181480)

5. Performance Studies

Performance testing was conducted on the NuTrac™ Pelvator Pelvic Muscle Trainer to demonstrate the integrity, suitability and substantial equivalence of the device

6. Conclusion

Based upon the Indications for use and performance studies NuTrac™ Pelvator has been shown to be substantially equivalent for its intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Verity Scientific Ltd.
% Mr. Brent Reider
President
International Trade Group, Inc.
4663 Kate Lane
OXFORD OHIO 45056

JUL 14 2009

Re: K083704
Trade/Device Name: NuTrac™ Pelvator, Model PEL 200
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: Class II
Product Code: KPI
Dated: June 30, 2009
Received: July 6, 2009

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083704

Device Name: **'NuTrac™ Pelvator'**

Indications For Use:

The **'NuTrac™ Pelvator'** Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women

Federal (USA) law restricts this device to sale by or on the order of a physician

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083704