SEP 1 2 2008

SECTION 5.0

NE Services Ltd
14D iPark
Innovation Drive
HU5 1SG
UK

510(k) Summary

1. **General Information**

Trade Name of Device:	**'Kegel8'**
Common/Usual Name:	Pelvic muscle trainer
Classification Name:	Non-implanted electrical continence device
Submitters Name and Address:	NE Services Ltd 14D iPark Innovation Drive HU5 1SG UK Tel +44 (0) 1482 873377 Fax+44 (0) 1482 873570
Manufacturer:	Mantra International (HK) Ltd Registration number 3003741750

2. **Device Description**
The **'Kegel8'** 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 **'Kegel8'** 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 **'Kegel8'** 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 **'Kegel8'** Pelvic Muscle Trainer is substantially equivalent to:
Athena Pelvic Muscle Trainer II (K033256).

5. Performance Studies

Performance testing was conducted on the Kegel8 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 Kegel8 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

SEP 1 2 2008

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

Re: K081480
Trade/Device Name: 'Kegel8' Pelvic Muscle Trainer
Regulation Number: 21 CFR 876.5320
Regulation Name: Non-implanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: August 28, 2008
Received: September 5, 2008

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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
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): K081480

Device Name: '**Kegel8**'

Indications For Use:

The '**Kegel8**' 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 K081480