

# Orelle Corporation Limited

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**510(k) Summary**

K121902

JUN 6 2013

**Submitter:**

Orelle Corporation Ltd  
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Seattle, Washington 98109  
Telephone: (206) 420-4703  
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**Contact:**

Patricia Coombes  
Chief Executive Officer

**Summary Prepared:**

May 24, 2013

**Trade Name:**

NatraTone®

**Regulation Name:**

Perineometer

**Classification Regulation:**

21 CFR 884.1425  
Class II Device

**Product Code:**

85 HIR

**Predicate Device:**

K021115 – The Naissance Holdings, LLC 'GyneFlex Perineometer'

**Device Description:**

NatraTone® is a pelvic floor muscle exerciser. It is a single, reusable device that comes into contact with the vaginal mucosal membrane for a limited (<24 hours) duration per each use. The device is 3.25 inches in length, 1.35 inch in width at its bulbous base end and weighs 1 ounce or 28 grams. The registered trade name 'NatraTone' is embedded in the thumb-hold area of the device. The device is fully inserted to sit low in the vagina in contact with the perineal muscles.

**Indications for Use:**

The NatraTone® is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, Urinary Incontinence in Women.

# Orelle Corporation Limited

## Predicate Device Comparison:

| Feature                                    | NatraTone®  | GyneFlex (K021115)  |
|--|---|---|
| Intended Use                               | Treatment of urinary incontinence   | Treatment of urinary incontinence   |
| Design                                     | Symmetrically S-shaped  | V-shaped  |
| Mechanism of action                        | Strengthen the perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions | Strengthen the perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions |
| Material                                   | Molded medical grade polycarbonate  | Molded medical grade plastic polymer  |
| Color                                      | Natural color   | Multiple color  |
| Sterilization                              | Clean, but not sterile  | Clean, but not sterile  |
| Prescription                               | Not required  | Not required  |
| Single Patient Device                      | Yes   | Yes   |
| Anatomical Sites                           | Intra-vaginal   | Intra-vaginal   |
| Reusability                                | Yes   | Yes   |
| Duration of Use                            | Transient   | Transient   |
| Instructions                               | Instructions Manual for patient home use  | Instructions Manual for patient home use  |
| Regular Visits to Medical Service Provider | Not required  | Not required  |
| Maintenance                                | Clean with soap and water; towel dry  | Clean with soap and water; towel dry  |
| Packaging                                  | Training Aid, Carry Case, Sealable plastic bag for Carry Case, and Instructional Manual in cardboard box      | Training Aid and Manual in cardboard box  |

## Material Safety

NatraToner is manufactured with Lexan resin HP4-1H111 that is used in 510(k)-cleared Kolpexin Sphere (K032664). The manufacturing process is identical and there are no additional materials, additives or colorants added to the NatraToner during the manufacturing process or at any other time.

## Conclusion

The information in this 510(k) demonstrates that the subject Orelle Corporation NatraTone® is substantially equivalent to the existing GyneFlex device (K021115) with respect to safety and effectiveness.



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

June 6, 2013

Orelle Corporation Ltd.  
% Ms. Patricia Coombes  
CEO  
7 Highland Drive, Ste. 704  
SEATTLE WA 98109

Re: K121902  
Trade/Device Name: NatraTone®  
Regulation Number: 21 CFR§ 884.1425  
Regulation Name: Perineometer  
Regulatory Class: II  
Product Code: HIR  
Dated: May 24, 2013  
Received: May 29, 2013

Dear Ms. Coombes:

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,

**Benjamin R. Fisher -S**

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Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

**510(k) Number:** K121902

**Device Name:** NatraTone®

**Indications for Use:**

NatraTone® is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, Urinary Incontinence in women.

Prescription Use: \_\_\_\_\_

AND/OR

Over-The-Counter Use:  \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher, S  
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\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and  
Urological Devices

510(k) Number \_\_\_\_\_ K121902