DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 4, 2014

Devon Medical Products
c/o Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K142168
Trade/Device Name: Nature's Bond 600, Nature's Bond 603
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: Class II
Product Code: HGX
Dated: November 19, 2014
Received: November 20, 2014

Dear Mark Job:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142168

Device Name
Nature's Bond 600
Nature's Bond 603

Indications for Use *(Describe)*
Nature's Bond breast pump is a single user device intended for lactating women to express and collect milk from their breasts to complement breast feeding.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## Section 5: 510(k) Summary

# 510(K) SUMMARY

### Submitter:

Devon Medical Products
1100 First Avenue, Suite 202
King of Prussia, PA 19406

### Contact Person:

Ruth Wu, CCO
Phone: 610.757.4103
Fax: 610.930.4035

### Common Classification & Proprietary Names:

Common Names: Breast Pump
Proprietary Name: Nature's Bond 600
Nature's Bond 603

### Date Prepared:

September 12th, 2014

### Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the Nature's Bond 600/603.

| Classification Name | 21 CFR Section | Product Code | Class |
|---|---|---|---|
| Pump, Breast, Powered | 884.5160 | HGX | II |

### Predicate Devices:

The Nature's Bond 600/603 Breast Pump is substantially equivalent to the following.

| Predicate Device | Manufacturer | 510(k)# |
|---|---|---|
| Powered Breast Pump | Lansinoh | K122474 |

### Device Description

The Nature's Bond series of breast pumps are electriconically powered suction devices used to express and collect breast milk from lactating mothers. The Nature's Bond series is comprised of two pumps, the model 600 and the model 603. The Nature's Bond breast pump system consists the pump, breast shields, tubing, power cord, bottle and cap, valve, and carrying bag exclusively for the model 603.

All available accessories are included in the Nature's Bond 600/603 package. Customers may purchase additional accessories if needed. Below is a list of all accessories included in the package:

- 2*80mm Breast Shield
- 2*76mm Breast Shield
- 2*74mm Breast Shield
- 2*Bottle

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- 2*Valve
- 1*Tubing

Both models of the Natuer's Bond breast pump is a software driven pump made from plastic. The details of the materials can be found in the bill of material. The pump can provide a pressure range from 0 mmHg to 206 mmHg. The model 603 has battery power (6 AA batteries) while the model 600 is only AC powered. While in using, the breast shields are in contact with human body. The device is design to be used by a single patient through one lactating period.

The device is designed for home use and is non-sterile.

Both pumps are the same in operation, use and design with the exception that the model 603 has the option to be battery powered. The pump provides intermittent suction in 6 different vacuum pressure settings to the breast to stimulate milk expression. The breast shields provide a seal around the breast to facilitate the suction. The bottles and caps are used to collect and store the milk. The tubing is used to connect the pump to the shields. The carrying bag is used to store all components when not in use.

### Indications For Use:

Nature's Bond breast pump is a single user device intended for lactating women to express and collect milk from their breasts to complement breast feeding.

### Technological Characteristics:

**Comparison**

The manufacturer believes that the technological characteristics of the Nature's Bond 600/603 are substantially equivalent to those of the predicate devices.
The Nature's Bond 600/603 has very similar components to its predicate device and has same principles of operation. Both the predicate device and the Nature's Bond 600/603 consist of an electrically generated source of compressed air; tubing to convey the pressurized air to the flange. The flange is connected to a collection container to store the expressed milk just like the predicate devices. Both devices have two modes of suction to express milk and with similar pressure ranges of those modes. Performance Testing was performed to compare the technological features of the two devices (subject and predicate), to show that the pressure at the breast shield was comparable between the subject and predicate devices. From this performance testing, it was found that the pressure applied to the breast through the breast shield of the subject device and the predicate device are comparable.

### Determination of Substantial Equivalence

| Feature | Nature's Bond 600/603 | Lansinoh Powered Breast Pump | Discussion of Differences |
|---|---|---|---|
| **Manufacturer** | Devon Medical Products | Lansinoh | Different Manufacturers |
| **FDA 510(k)** | K142168 | K122474 | Different K #'s |
| **Indications for Use** | Nature's Bond breast pump is a single user | The Powered Breast Pump is intended to | Same |

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| | | | |
|---|---|---|---|
| | device intended for lactating women to express and collect milk from their breasts to complement breast feeding. | express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user. | |
| **Single/Dual Mode** | Yes/Yes | Yes/Yes | Same |
| **Internal Construction** | Pump, battery (603 only), main PCB, switch valve | Pump, battery, main PCB, switch valve | Same |
| **Screen** | LED Lights | LCD Display | Similar,<br>Though the Lansinoh has a LCD display, and Nature's Bond utilizes LED lights, the same information is still provided to the user |
| **Modes** | 2 | 2 | Same |
| **Stimulation Mode** | High Frequency, Low Pressure | High Frequency, Low Pressure | Same |
| **Expression Mode** | Low Frequency, High Pressure | Low Frequency, High Pressure | Same |
| **Max Measured Vacuum Pressure** | 206.1 mmHg | 229.2 mmHg | Similar, The maximum vacuum pressure is slightly lower on the Nature's Bond than the Lansinoh, which poses no harm. |
| **Pump Style** | DC Motor | DC Motor | Same |
| **Energy Used** | AC<br>Battery (603 Model) | AC<br>Battery | Same |
| **Energy Used** | AC & Battery (603 Model) | AC & Battery | Same |
| **Materials Used** | All food or human contacting components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177, and 178 | All food or human contacting components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177, and 178 | Same |

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| | |
|---|---|
| and ISO 10993 | and ISO 10993 |

### Food or Patient Contacting Parts

| Part | Contact |
|---|---|
| **Breast Shield (Small, Medium, Large)** | Patient Contact |
| **Bottle** | Food Contact |
| **One-Way Valve** | Food Contact |

### Performance Testing

Bench and laboratory testing was performed and assures that the product meets its specifications. The manufacturer believes that the technological characteristics of the Nature's Bond 600/603 are substantially equivalent to those of the predicate devices. The following tests were conducted to ensure Nature's Bond Breast Pump 600/603 meet their specifications.

| Tests |
|---|
| **Nature's Bond 603 Battery Depreciation Test** |
| **Breast Pump Performance Pressure Test** |
| **One-Way Valve Test** |

During all above tests, the subject devices have software version 00.01, which is the version verified and validated in the software section.
The food contacting materials of the device are in compliance with 21 CFR 175.300, 177.1210, 177.1520, 177.1640, and 177.2600.

### Standards

The Nature's Bond 600/603 conforms to the following standards:

IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard:
AAMI ES 60601-1: 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
IEC 60601-1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 10079-1, Medical suction equipment Part 1: Electrically powered suction equipment – Safety requirements
ISO 10993-5 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-12 Biological evaluation of medical devices Part 12: Sample preparation and reference materials

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ISO 10993-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ISO 10993-2:2006 Biological evaluation of medical devices -- Part 2: Animal welfare requirements
ISO 10993-11:2006 Biological Evaluation of Medical Devices -- Part 11: Tests for Systemic Toxicity

### Statement of Substantial Equivalence

The Nature's Bond 600/603 is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.

### Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Devon Medical Products, believes that the Nature's Bond 600/603, is substantially equivalent to the predicate devices as described herein.