MAYBORN
BABY AND CHILD

MAY 31 2012

510K Submission

Product Closer to Nature – Single Electric Breast Pump – New Horn

Project File Number – DEV 1063 - update

SECTION 5: 510(k) Summary

Submitter

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Date Prepared

March 2012

Device Information

Trade name:	Closer to Nature
Common name:	Single Electric Breast Pump
Classification Name:	Pump, breast, powered
Review Panel:	Obstetrics / Gynecology
Product Code:	HGX
Device Class:	2

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Indication for Use

Tommee Tippee® Closer to Nature® Single Electric Breast Pump is personnel use item for lactating women and is intended for one user to express and collect milk from the breast.

Device Description

This Single Electric Breast Pump product is designed to provide everything a mother will need to start expressing, storing and feeding. The pump unit has 4 alternate settings of suction level during expression. The collect and protect breast milk storage system enables the user to express directly into the small graduated 2oz pod, which fits into "Closer to Nature" bottles for feeding. The product is designed to use, one pod size per 5oz bottle and 2 pod sizes for a 9oz bottle for expressing, storing and feeding. This device is mains or battery powered.

Included with the Single electric breast pump motor unit and vacuum system are:

1 off - Feeding bottles 5oz with teats - as per Mayborn Single Electric Breast Pump – K110343

1 off - Milk storage lids - as per Mayborn Single Electric Breast Pump – K110343

2 off - Milk storage pods as per Mayborn Single Electric Breast Pump – K110343

6 off - Disposable Breast pads - as per Mayborn Single Electric Breast Pump – K110343

1 off - Spare valves – K113664

1 off - Hygiene cover – as per Mayborn Single Electric Breast Pump - K110343

1 off - Steri Box – K110343

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Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name
K110343	*Tommee Tippee Closer to Nature Single Electric Breast Pump*
K113664	*Tommee Tippee Closer to Nature Double Electric Breast Pump*

Device Comparison to Legally Marketed Device

Following is a comparison chart outlining differences and similarities between the new Tommee Tippee Closer to Nature Single Electric Breast Pump, and the Current Tommee Tippee Closer To Nature Electric Breast Pump cleared under 510k K110343 and K113664.

	New Product	Predicate	Predicate
Device Name	Tommee Tippee Closer to Nature Single Electric Breast Pump	Tommee Tippee Closer to Nature Single Electric Breast Pump	Tommee Tippee Closer to Nature Double Electric Breast Pump
Manufacturer	Mayborn Group Limited	Mayborn Group Limited	Mayborn Group Limited
510(k) number	To be assigned	K110343	K113664
Product Code	HGX	HGX	HGX
Classification	2	2	2
Intended use	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160
Power Source	5V DC Electrical Adaptor OR 4 x AA Batteries	5V DC Electrical Adaptor OR 4 x AA Batteries	9V DC Electrical Adaptor OR Battery
Pump type	Reciprocating Diaphragm	Reciprocating Diaphragm	Reciprocating Diaphragm
Single Pumping	Single	Single	Single
Suction Levels	Yes – 1 Pre set on starting and 3 User Selectable Separate Speed Rates	Yes – 1 Pre set on starting and 3 User Selectable Separate Speed Rates	Yes – 1 Pre set on starting and 4 User Selectable Separate Speed Rates
Highest Vacuum Setting - single pump	233mmHg	269mmHg	300mmhg
Lowest Vacuum Setting - single pump	150mmHg	135mmHg	150mmHg
Adjustable Cycle Speed	No	No	No
Range of Cycle Speeds	36	41	36
Overflow Protection	Yes	No	Yes
Breast Cup-to-Breast Interface	Soft Silicone Wacker R401 and Toshiba TSE 260	Soft Silicone Wacker R401	Soft Silicone Wacker R401 and Toshiba TSE 260

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Both of the *Current Tommee Tippee Closer To Nature Electric Breast Pumps (K110343 & K113664)* and the new Closer to Nature Single Electric Breast Pump are identified by the FDA as Product code HGX under CFR section 884.5160.

Both Units use batteries or mains adaptor.

Both units use a single diaphragm / piston pump.

The Horn (DEV 1063-4) used on the current Closer to Nature Breast Pumps K110343 and K113664 has been utilised on the new Closer to Nature Single Electric Pump and is the approved with respect to biocompatibility.

Non Clinical Testing

Mayborn Baby and Child during the development of the product identified six key comparative areas which would ensure the safety and integrity of the new Closure to Nature Single Electric Breast Pump would match or exceed the ability of the *Current Tommee Tippee Closer To Nature Single Electric Breast Pump (K110343)*.

These cover the following:

1. Pump vacuum when installed in the housing - mmHg
2. Suction flow rate – millilitres per minute
3. Noise Level – decibel level
4. Materials
5. Electrical Safety.
6. Backflow protection

1. Pump vacuum when installed in the housing

The first key comparative area identified was the vacuum capability of the pump when installed in the housing. A direct comparison of the pumps was carried out as below.

Vacuum While Single Pumping

	New Product	The Predicate
Device Name	Tommee Tippee Closer to Nature	K110343
Setting 1	Stimulation	
Setting 2	150mmHg	135mmHg
Setting 3	220mmHg	205mmHg
Setting 4	233mmHg	269mmHg (REF 510K)

This shows there is no significant difference in the devices.

2. Suction flow rate

The second key comparative area identified was the suction rate of the pump in terms of its ability to flow liquid, this test used a newly design flow rate fixture to that used in the original breast pump submission. The comparison of the pumps identified the following:

Single Pump

	New Product	The Predicate
Device Name	Tommee Tippee Closer to Nature	K110343
Setting 1	Stimulation	
Setting 2	88ml/min	87ml/min
Setting 3	118ml/min	122ml/min
Setting 4	131ml/min	131ml/min

All tested on high suction over duration of 2 minutes 30 seconds.
Reservoir water level was maintained at 3 litres.
CTN Fast Flow teats used in rig.

This shows there is no significant difference in the devices.

3. Noise Level

The third key comparative area identified was the noise level of the pump in terms of being discreet. The comparison of the pumps identified the following based on the lowest, middle and highest settings.

	New Product	The Predicate
Device Name	Tommee Tippee Closer to Nature	K110343
Setting 4	68dba	68dba

This shows there is no significant difference in the devices.

4. Materials

The fourth key area identified was material selection; all the materials specified and tested for use in the new Closer to Nature Single Electric Breast Pump have been selected to ensure they meet the appropriate FDA regulations concerning food contact and or biocompatibility to ensure maximum protection of the infant from contaminated food and maximum comfort for the mother.

All milk and human contact components are manufactured from materials that meet FDA food additive criteria as set forth in Part 21 Code of Federal Regulations Parts 176, 177 and 178.

The skin contacting materials associated with the Single Electric Breast Pump satisfy all required biocompatibility testing in accordance with ISO 10993 parts 5 and 10 for skin contact.

This shows there is no significant difference in the devices.

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5. Electrical Safety

The fifth key comparative area identified was the Electrical safety of the. The unit and adaptor are the same electrical construction as the *Current Tommee Tippee Closer To Nature Single Electric Breast Pump (K110343)* which has been tested to the applicable standards below.

Applicable standards

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1: 1988 + A1: 1991 +A2: 1995
UL 60601-1, 1st edition, Rev April 26 2006

Medical electrical equipment – EMC (Electromagnetic Compatibility Requirements)

IEC 60601-1-2: 2001 + A1: 2004

6. Back flow Protection.

Both the new Closer to Nature Single Electric Breast Pump and the *Current Tommee Tippee Closer To Nature Single Electric Breast Pump (K110343)* were tested to determine the angle at which backflow into the vacuum tube could be created.

It was found that the new diaphragm system in the Closer to Nature Single Electric Breast Pump created a physical barrier which stopped all backflow into the vacuum tube; this is a significant improvement in product reliability and eliminates the potential for miss use. This anti back flow system is the exact same system clear under 510K K113664 the Closer to Nature Double Electric Breast Pump

This shows the new Closer to Nature Single Electric Breast Pump has a significant improvement over the *Current Tommee Tippee Closer To Nature Single Electric Breast Pump (K110343.)*

Conclusion

The new Tommee Tippee Closer to Nature Single Electric Breast Pump, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. The device presents no adverse health effects or safety risks when used as intended.

The new Tommee Tippee Closer to Nature Single Electric Breast Pump has the same intended use and fundamental scientific technology as its predicate device – the *Current Tommee Tippee Closer To Nature Single and Double Electric Breast Pump (K110343 and K113664)*

The new Tommee Tippee Closer to Nature Single Electric Breast Pump was tested against its predicate, and was found to be substantially equivalent based on the summary information above and the detailed evaluation within this submission.

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

Mayborn Group Limited
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 31 2012

Re: K121322
Trade/Device Name: Closer to Nature Single Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: May 17, 2012
Received: May 18, 2012

Dear Mr. 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 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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BABY AND CHILD

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SECTION 4: Indications for Use

510(k) Number: K121322

Device Name:

Closer to Nature Single Electric Breast Pump

Indications for Use:

Tommee Tippee® Closer to Nature® Single Electric Breast Pump is personnel use item for lactating women and is intended for one user to express and collect milk from the breast.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121322

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