MAR 1 1 2011

SECTION 5: 510(k) Summary

Submitter

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Date Prepared

December 2010

Device Information

Trade name: closer to nature®
Common name: electric breast pump
Classification Name: pump, breast, powered
Review Panel: Obstetrics/Gynecology
Product Code: HGX
Device Class: 2

Indication for Use

Tommee Tippee Closer to Nature® Electric Breast Pump is used to express and collect milk from the breast of a lactating woman.

Device Description

This electric breast pump product is designed to provide everything a mother will need to start sterilizing, expressing, storing and feeding. The pump unit has 3 alternate settings: light, medium and high suction levels during expression. The collect and protect breast milk storage system enables the user to express directly into the small graduated 2 oz pot, which fits into "Closer to Nature" bottles for feeding. The product is designed to use, one pot size for expressing, storing and feeding. This device is Mains or Battery powered.

Included with the pump and vacuum system is:

Accessories

Sterilizer box - This doubles up as a storage case

Feeding Components

Feeding bottle with slow flow teat
2 Milk storage pots
Milk storage lid
6 Breast pads

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name	Manufacturer
K053052	Swing™ Breast pump	Medela AG, Switzerland

Device Comparison to Legally Marketed Device

Below is a comparison chart outlining differences and similarities between the Tommee Tippee® Closer to Nature® Electric Breast Pump, and the Medela AG, SwingTM electric breast pump.

	New Product	The Predicate
Device Name	Tommee Tippee® Closer to Nature®	Swing™
Manufacturer	Mayborn Group Limited	Medela AG
510(k) number	To be assigned	K053052
Product Code	HGX	HGX
Classification	2	2

	New Product	The Predicate
Intended use	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160
Power Source	6V DC four (4) AA batteries or electric adaptor	6V DC four (4) AA batteries or electric adaptor
Pump type	Reciprocating Diaphragm	Reciprocating Diaphragm
Single or Double Pumping	Single	Single
Adjustable Suction Levels	Yes - 4 Separate Speed Rates	Yes
Adjustable Cycle Speed	No	Yes
Overflow Protection	No	No
Highest Vacuum Setting [in Hg]	10.6	11.8
Lowest Vacuum Setting [in Hg.]	5.3	1.7
Range of Cycle Speeds	41 Fixed	45-72
Breast Cup-to-Breast Interface	Soft Silicone Wacker R401	Rigid Plastic with Soft TPE section

Both The Medala Swing (K053052) and the Closer to Nature Electric Breast Pump are identified by the FDA as Product code HGX under CFR section 884.5160.
Both Units use a standard 6v battery supply or mains adaptor.
Both units use a single diaphragm pump.
Both units generate a vacuum equivalent to approx 11inches of Mercury on the maximum setting.

Key Areas

Mayborn Baby and Child during the development of the product identified five key comparative areas which would ensure the safety and integrity of the Closure to Nature Electric Breast Pump would match or exceed the ability of the Medela Swing (K053052)

These cover the following:

1. Pump vacuum – direct measurement of the pumps used
2. Pump vacuum when installed in the housing
3. Lowest suction rate
4. Suction rate
5. Materials

The **first** key comparative area identified was the bare vacuum capability of the pumps when removed from the housing. A direct comparison of the pumps was carried out and the results

showed the Closer to Nature pump drawing a vacuum of -40kpa and the Medala Swing pump drawing a vacuum of -38kpa.

This shows there is no significant difference in the devices.

The **second** key comparative area identified was the vacuum capability of the pumps when installed in the housing. A direct comparison of the pumps was carried out and the results showed the Closer to Nature Electric Breast Pump was capable of drawing a vacuum up to -38kpa and the Medala Swing pump was capable of drawing a vacuum up to -36kpa.

This shows there is no significant difference in the devices.

The **third** key comparative area identified was the lowest vacuum capability of the pumps when installed in the housing and the pump is set up for simulated use. A direct comparison of the pumps was carried out and the results showed the Closer to Nature pump drawing a vacuum of -20kpa and the Medala Swing pump drawing a vacuum of -29kpa.

This shows the Closer to Nature Electric Breast Pump can draw a slightly lower vacuum during use by the mother.

The **forth** key comparative area identified was the suction rate of the pump in terms of its ability to flow liquid. The comparison of the pumps identified the following:

Closer to Nature Electric Breast Pump:
Time period = 2 minutes (120seconds)
Fluid Displaced = 180millilitres

Medala Swing Electric Breast Pump:
Time period = 2 minutes (120seconds)
Fluid Displaced = 150millilitres

This shows there is no significant difference in the devices.

The **fifth** key area identified was material selection; all the materials specified and tested for use in the Closer to Nature Electric Breast Pump have been selected to ensure they meet the appropriate FDA regulations concerning food contact and or bio compatibility 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 Electric Breast Pump will satisfy all required biocompatibility testing conducted in accordance with ISO 10993 for skin contact.

This shows there is no significant difference in the devices.

Conclusion

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

Tommee Tippee® Closer to Nature® Electric Breast Pump has the same intended use and fundamental scientific technology as its predicate device – the Medela® SwingTM Breast Pump (K053052).

Tommee Tippee® Closer to Nature® 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

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

Mayborn Group Limited
c/o Ms. Paula Wilkerson
Senior Staff Engineer – Medical Devices
Intertek
2307 E Aurora Road, Unit B7
TWINSBURG OH 44087

MAR 11 2011

Re: K110343
Trade Name: Closer to Nature® Electric Breast Pump
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product code: HGX
Dated: March 2, 2011
Received: March 4, 2011

Dear Ms. Wilkerson:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: Indications for Use

510(k) Number: ~~TBA~~ K110343

Device Name:

Closer to Nature® Electric Breast Pump

Indications for Use:

Tommee Tippee® Closer to Nature® Electric Breast Pump is used to express and collect milk from the breast of a lactating woman.

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)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110343