OCT 09 2008

K082802

510(k) Summary of Safety and Effectiveness
August 8, 2008

1. Submitter Information

a. Address: Learning Curve Brands
100 Technology Drive Suite 2A
Stoughton, MA 02072
Tel. 781-341-6250

b. Contact Person: Supravan Khongkruaphan
Product Integrity Manager

2. Name of the Device

a. Trade Name : miPump ™

b. Classification Name : Power Breast Pump

c. Common/Usual Name

1. miPump Single Electric / Battery Breast Pump Y4612
2. miPump Double Electric / Battery Breast Pump Y4613
3. miPump Deluxe Double Electric / Battery Breast Pump Y4614

3. Classification of the Device

Per 21 CFR 884.5160 states that power breast pump are class II medical devices.

4. General Device Description

The miPump Electric / Battery Breast Pump are quiet, small, safety and effective system for express milk from the breast. It has electrical pressure control pumping system to generate suction. This device is designed with eight suction levels, which are selectable by the user via pressing the suction button. It is powered either by four (4) AA batteries (not included with package) or powered electrically by utilizing the AC adaptor (6V) which is provided in the package and can be plugged into any standard wall outlet.

No.	Item	
3.	**Location in 510(k):**	Device Description – Section 11
	Finding/Question Noted:	The Device Description does not identify all of the accessories of the device. Please refer to the device labeling and describe each accessory in the device description (i.e. pads, milk storage, handle, etc). These accessories should also include a reference if they are currently cleared devices, are part of another device that is cleared, or other. If they are currently cleared device, please provide the manufacturer and FDA K number for each accessory. If any of these are part of a Kit, please provide a Kit Certification. (http://www.fda.gov/cdrh/ode/odecl874.html)
	Sponsor's Response:	Revised Device Description section to include all of the accessories and kit of the device (page 24), also provide kit certification (Attachment 3). Addition, describe how the kit and accessory are packed in package.
	Third Party Summary:	

Device Description

The miPump Electric / Battery Breast Pump is a quiet, small, safe and effective system to express milk from the breast. It has electrical pressure control pumping system to generate suction. This device is designed with eight suction levels, which are selectable by the user via pressing the suction button. It is powered either by four (4) AA batteries (not included with package) or powered electrically by utilizing the AC adaptor (6V) which is provided in the package and can be plugged into any standard wall outlet. (See Attachment I for Drawing, Label and Instruction for use).

The principle of operation of the miPump Electric / Battery Pump is as follows:

1. Turn pump on by pressing and holding power button down for three seconds. Power light will illuminate indicating pump is on. The pump always powers on at lowest level.
2. To pump sit upright, Grasp the bottle by 3-way adaptor and insert breast into the Flexi-Fit shield. Your breast should completely fill shield.
3. To increase suction, press the "+" button. There are eight suction levels. The green suction indicator lights illuminate as suction is increased. When the last light is illuminated, the highest suction setting has been reached.
4. To reduce suction, press the "-" button. To immediately reduce suction, turn pump off and remove shield from breast.

Learning Curve Brands intends to market the miPump Electric / Battery Breast Pump with following components as Table below. Materials for all components used in the manufacture of the miPump Electric / Battery Pump that come in contact with the user's skin and breast milk are manufactured from materials that meet FDA food additive criteria per Title 21, CFR, sections 175-178. There is no information suggesting that there have been any tissue irritation, sensitization, or cell damage response with these materials. See section 15 for supportive information concerning material testing.

Kit of miPump Electric / Battery Breast Pump		
Parts List	**Material**	**For SKU #**
Pump Assembly***/*	Injection Molded ABS	Y4612 / Y4613 / Y4614
AC/DC Adapter	Class2Transformer;InputAC120V60Hz 9W output Color Black and White	Y4612 / Y4613 / Y4614
Drip edge 3-way bottle adapter***/*	Injection Molded polypropylene Color Clear	Y4612 / Y4613 / Y4614
Basic One-way Angled 9ml Flapper Valve Assembly***/*	Injection Molded PP ;with Silicone, Flapper Color Natural	Y4612 / Y4613 / Y4614
Flexi-Fit Breast Pump Shield***/*	Liquid Injection Molded Silicone Color Clear/Natural	Y4612 / Y4613 / Y4614
Pump Hose***/*	PVC non Phthalate	Y4612 / Y4613 / Y4614

Accessories of miPump Electric / Battery Breast Pump		
Parts List	**Material**	**For SKU #**
5 oz Soothie Bottle	PP	Y4612 / Y4613 / Y4614
Soothie Bottle Nipple	Silicone,Stage1	Y4612 / Y4613 / Y4614
Soothie Bottle Collar	Injection Molded PP	Y4612 / Y4613 / Y4614
Soothie Bottle Hood	PP	Y4612 / Y4613 / Y4614
2pk Milk Storage Bags	LDPE	Y4612 / Y4613 / Y4614
Milk Storage wide closure covers	Injection Molded PP Color White	Y4612 / Y4613 / Y4614
Tote	PMS 462U(brown) and PMS 291C(blue)	Y4612 / Y4613 / Y4614
Instruction Booklet	Color White	Y4612 / Y4613 / Y4614
Slip Sheet	Color PMS Yellow	Y4612 / Y4613 / Y4614
2 pk Lanolin pads	Layer of Thermo-bond Polypropylene non-woven fabric	Y4613 , Y4614 only
Pump Handle	ABS	Y4613 , Y4614 only
Bottle Adaptors	PP	Y4614 only
Insulated Bottle Carrier	Micro Fiber	Y4614 only
Reusable Cold Packs	PE cover	Y4614 only

*** Components come in contact with the user's skin and breast milk

* Complied with FDA 21 CFR 175-178 Indirect Food Additive in BV test Report (5108 196-0003)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Learning Curve Brands/The First Years
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K082802
Trade Name: miPump Electric/Battery Breast Pump: miPump Single Electric/ Battery Breast Pump Y4612, miPump Double Electric/Battery Breast Pump Y4613, and miPump Deluxe Double Electric/Battery Breast Pump Y464
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 18, 2008
Received: September 24, 2008

Dear Mr. Conry:

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

Indication for Use

510(k) Number (if known): K082802

Device Name: miPump Electric / Battery Breast Pump

- miPump Single Electric / Battery Breast Pump Y4612
- miPump Double Electric / Battery Breast Pump Y4613
- miPump Deluxe Double Electric / Battery Breast Pump Y4614

Indication For Use: Powered Breast Pump to express milk from the breast.

Prescription Use _____ And/Or Over the Counter Use _X_.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082802