Traditional 510k Summary

AUG 1 1 2011

General Information

1. **Applicant:**

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Great Neck, NY 11021
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2. **Contact Person:**

Mr. Chien-Ming GOH (Andrew)
Vice President
Genadyne Biotechnologies Inc.
65 Watermill Lane,
Great Neck, NY 11021
Tel: 516-487-8787
Fax: 516-487-7878
Andrew@genadyne.com

3. **Trade/Proprietary Name Including Model Number of Device:**

   Lucina-Melodi Powered Breast Pump

4. **Common Name or Classification Name (21 CFR Part 807.87) of Device:**

   Powered Breast Pump (21 CFR 884.5160, Product Code HGX)

5. **Class in which Device has been placed:**

   Class II

6. **Reason for Premarket Notification:**

   Introduction of a new device.

7. **Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):**

   Medela Pump In Style Breast Pump (K950750)
   Medela Pump In Style Advance Breast Pump (K031614)

8. Description of the Device

The Lucina-Melodi Powered Breast Pump is an advanced breast pump powered by a smart software. It has a 2 phase suction cycle. It is portable and is battery powered, with a rechargeable battery build in the system. It weighs less than 1kg. It is intended for single user usage, and can be use on both breasts at the same time. The device has a build in color LCD screen, and easy to use buttons and graphic user interface.

9. Intended use of the Device

The Lucina-Melodi Powered Breast Pump is intended to express and collect milk from the breasts of lactating women.

10. Description of Device

The device can be run on battery power and also while plugged in to the AC adapter. Internally, it gets its suction from a diaphragm motor. The PCB board will control the speed and the suction of the motor to provide optimal suction or based on the settings that the user provided. The device has a smart 2 phase software running which provide 2 different speeds to the user. Phase 1 runs at a higher speed than phase 2. The device has a large color LCD screen, with 6 easy to use buttons.

Comparative Information

11. Comparison to Predicate Device

Table of Comparison to Legally Marketed Device:

Comparative Information		
	Predicate Device	**New Device**
Company	Medela, Inc.	Genadyne Biotechnologies
Device Name	Pump in Style Advance	Lucina-Melodi
510 (K) Number	K031614	
Technical Data		
Vacuum Range	50-250 MMHG	50-250 MMHG
Power Requirements	60 Hz	19 V, 30W
Battery Type	Non-Rechargeable Ni-MH	Rechargeable Li-Ion
Dimensions	11 5/8 x 7 7/8 x 11 ¾ inches	6 x 4 x 2.36 inches
Weight	9 Lbs	1.5 Lbs
Dual Pumping	Yes	Yes
Accessories		
Filter	No	Yes
Breast Shields	Yes	Yes
Storage Bag	Yes	Yes
Baby Bottles	Yes	Yes
Valve flanges	Yes	Yes
Tubing	Yes	Yes
Splitter	No	Yes
Sterile	Non Sterile	Non Sterile

Indications for Use		
	The Pump In Style Advanced Breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.	Intended use of the powered breast pump is to express and collect milk from the breasts of lactating women.
Testing		
	NA	IEC 60601-1-2
	NA	FCC part 15 Class B
	NA	EN 55011
	NA	IEC 61000-4-2
	NA	IEC 61000-4-3

Discussion of Similarities and Differences
Device Similarities

Indication for use
The Lucina-Melodi Powered Breast Pump and the Medela Pump In Style Advanced Breast Pump are both intended to express and collect milk from the breasts of lactating women. The indication for use is identical.

Technological characteristics
Functional designs are the same, where by the system services as a suction device which is connected to a collection bottles where by breasts shields are use to place onto the breasts to collect milk. All devices are sold non-sterile. Devices are for dual pumping of breasts, and have the same accessories to collect milk.

Basic Product Function
The Lucina-Melodi and the predicate device have the same product function of generating a vacuum to provide general use suction and collection of milk into a bottle.

Device Differences

In comparison to the predicate devices, the Lucina-Melodi has several differences which do not affect the device safety and effectiveness of the intended use. These differences are described in further detail below.

Lucina-Melodi
The Lucina-Melodi is lighter in weight and smaller in dimension. It also have a rechargeable battery so that users could use it without it being plugged onto the wall all the time. In all other aspects, the Lucina-Melodi Powered Breast Pump and the predicate device are substantially equivalent.

12. Conclusions:

I believe that the Lucina-Melodi Powered Breast Pump is substantially equivalent to the predicate device. Results from the bench test, proves that the data collected is equally as good as the predicate.
The pressure at different levels was consistent and stable, in both single and double pumping usage. In another pressure vs time test, the peak pressure was consistent throughout the whole test at several pressure levels. Lastly, in the cycles per minute vs time test, the CPM were consistent over time.

13. Determination of Substantial Equivalence

Bench testing were done on the Lucina-Melodi Powered Breast Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Chien-Ming Goh
Vice President
Genadyne Biotechnologies Inc.
65 Watermill Lane
GREAT NECK NY 11021

AUG 11 2011

Re: K102516
Trade/Device Name: Lucina-Melodi Powered Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 26, 2011
Received: July 27, 2011

Dear Mr. Goh :

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

Indications for Use

510(k) Number (if known): K102516

Device Name: Lucina-Melodi Powered Breast Pump

Indications For Use:

The Lucina-Melodi Powered Breast Pump is intended to express and collect milk from the breasts of lactating women.

Prescription Use _____ **OR** **Over-The Counter Use** __X__
(Per 21 CFR 801 Subpart D) **(21 CFR 807 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 K102516