Traditional 510k Summary

MAY 10 2012

General Information

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.487.7878
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.487.7878
3.	**Trade/Proprietary Name Including Model Number of Device**	Lucina-Melodi Advance 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 an already approved device (K102516) with a new indication for use.
7.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	Medela Symphony Powered Breast Pump (K020518) Lucina-Melodi Powered Breast Pump (K102516)
8.	**Brief Description of Device**	The Lucina Melodi Advanced Breast Pump is a battery powered breast pump powered by a smart software. It has a 2 phase suction cycle. Phase 1 runs at a higher speed than phase 2. It is portable and is battery powered, with a rechargeable battery build in the system. It weighs less than 1 kg. it is intended for continuous usage from User A to User B to User C etc. It can be use on both breasts at the same time as well as single breast one at a time. The device has a build in color LCD screen, and east to use buttons and graphic user interface. 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 sets at.
9.	**Summary of Technological Characteristics**	The technology of the Lucina-Melodi Advance Breast Pump is identical to the predicate device (Lucina-Melodi Powered Breast Pump – K102516) and there are no technical differences which would raise new aspects regarding safety and effectiveness. Both employ the same software and hardware architecture.
10.	**Intended Use of the Device**	The Lucina-Melodi Advance Breast Pump is intended to express and collect milk from the breast of lactating women. This device may be used by more than one user if the collection kit is changed.

11. Comparison to Predicate Device

Table of Comparison to Legally Marketed Device:

Comparative Information			
	Predicate Device #1	Predicate Device #2	New Device
Company	Medela Inc.	Genadyne Biotechnologies	Genadyne Biotechnologies
Device Name	Medela Symphony Powered Breast Pump	Lucina-Melodi Powered Breast Pump	Lucina-Melodi Advance Breast Pump
510 (K) Number	K020518	K102516	-
Technical Data			
Vacuum Range	50-250 mmHg	50-250 mmHg	50-250 mmHg
Power Requirements	120V ~, 50/60 Hz	19 V, 30W	19 V, 30W
Battery Type	None	Rechargeable Li-Ion	Rechargeable Li-Ion
Dimensions	8" x 7" x 4"	6" x 4" x 2.36"	6" x 4" x 2.36"
Weight	~5 lbs.	1.5 lbs.	1.5 lbs.
Dual Pumping	Yes	Yes	Yes
Accessories			
Filter	No filter present	0.2µm hydrophobic bacteria filter	0.2µm hydrophobic bacteria filter
Breast Shields	Yes	Yes	Yes
Storage Bag	Yes	Yes	Yes
Valve Flanges	Yes	Yes	Yes
Tubing	Yes	Yes	Yes
Splitter	Yes	Yes	Yes
Sterile	Non Sterile	Non Sterile	Non Sterile
Indication For Use	The Symphony Powered Breast Pump is intended to express and collect the mother's milk from the breasts of a lactating woman, thus identical to the predicate devices.	Intended use of the powered breast pump is to express and collect milk from the breasts of lactating women.	The Lucina-Melodi Advance Breast Pump is intended to express and collect milk from the breast of lactating women. This device may be used by more than one user if the collection kit is changed.
Testing			
	NA	IEC 60601-1-2	IEC 60601-1-2
	NA	FCC part 15 Class B	FCC part 15 Class B
	NA	EN 55011	EN 55011
	NA	IEC 61000-4-2	IEC 61000-4-2
	NA	IEC 61000-4-3	IEC 61000-4-3

Discussion of Similarities and Differences **Device Similarities**
Indication for use The Lucina-Melodi Advance Breast Pump, and it's predicate devices are all intended to express and collect milk from the breasts of lactating women.
Technological characteristics The software and hardware design for both the Lucina-Melodi Advance Breast Pump and the Lucina-Melodi Powered Breast Pump are exactly identical. The kits and bottles are also exactly identical.
Device Differences
Indication for use Although the basic function and indication for use are the same, the Lucina-Melodi Advance Breast Pump and the Medela Symphony Powered Breast Pump can be used with multiple user, 1 user at a time, whereas the Lucina-Melodi Powered Breast Pump is only intended for single user only.
Technical Specs The Lucina-Melodi models are lighter in weight and smaller in size as compared to the Medela Symphony. The Lucina-Melodi models are portable and can be used battery powered or by charging it with the AC adapter, while the Medela Symphony can only be used while it is being plugged in to an AC power source. The Lucina-Melodi models have a rechargeable battery build in, but the Medela Symphony does not.

12.	**Additional Bench Testing**	Bench testing was done on the Lucina-Melodi Advance Breast Pump. Continuous usage test to prove that the machine can withhold strenuous and continuous usage, as well as post testing for consistency to measure pressure over time to ensure that the pressure stays consistent within a defined suction range. A microbiological tightness validation test for the membrane of the barrier diaphragm in the breast shield set was also conducted.
13.	**Conclusion & Determination of Substantial Equivalence**	Based upon the information presented above, it is concluded that the proposed Lucina-Melodi Advance Breast Pump is safe and effective for the intended use, and is substantially equivalent to the predicate devices.

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

Mr. Chien-Ming (Andrew) GOH
Vice President
Genadyne Biotechnologies, Inc.
16 Midland Ave
HICKSVILLE NY 11801

MAY 10 2012

Re: K112856
Trade/Device Name: Lucina-Melodi Advance Breast Pump for multiple users
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: April 30, 2012
Received: May 1, 2012

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,

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

Indications for Use

510(k) Number (if known): K112856

Device Name: Lucina-Melodi Advance Breast Pump
Indications For Use:

The Lucina-Melodi Advance Breast Pump is intended to express and collect milk from the breast of lactating women. This device may be used by more than one user if the collection kit is changed.

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

Elaine H. Burge for Benjamin Fisher

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112856