K043098

DEC 15 2004

Gerber

GERBER PRODUCTS COMPANY
A NOVARTIS COMPANY

510(k) Summary
September 20, 2004

Submitter:	Gerber Products Company 445, State Street Fremont, MI 49413-0001 Phone: 231 928 2831 Fax: 231 928 2964
Contact Name:	Dr. Nicholas Hether Director, Product Safety & Regulatory Sciences
Trade Name:	Gerber Double Electric Breast Pump
Common Name:	Electric Breast Pump
Classification Name:	Powered Breast Pump 21 CFR 884.5160 (85 HGX) Class-II
Substantial Equivalence:	The Gerber Double Electric Breast Pump is substantially equivalent to the following legally marketed predicate devices:

Company	**Product Name**	**510(k) clearance#**
Medela	Pump-in-Style	K031614
Ameda Egnell	Purely Yours	K973501
Playtex	Breast Pump	K022594

General Description:
The Gerber Double Electric Breast Pump is a simple and effective system for expressing milk from a lactating women's breast(s). The device includes the following components: a pump base, flexible tubing, a funnel assembly, a carrying bag, and accessories (e.g. bottles, nipples, and disposable nursing pads).

Device Description:
The device is powered by a variable speed power supply that drives a diaphragm pump. The diaphragm pump creates the negative pressure required to extract breast milk. The breast pump is capable of providing a variable vacuum and massage like motion. A maximum vacuum of 240 mm Hg can be applied to one or both breasts.

Design and materials:
All components that may come in contact with the milk are manufactured from materials that meet FDA food contact criteria. The materials that contact the breast have been tested for biocompatibility.

Intended Use:
An electrically powered breast pump with settings, for expressing milk from the breasts of a lactating woman.

Technological Characteristics of the Device:
The Gerber Double Electric Breast Pump is substantially equivalent to other powered breast pumps that are available for commercial distribution. A chart showing the similarities and differences of the proposed powered breast pump and the predicate powered breast pumps follows:

Comparison of Predicate Devices				
	New device	**K031614**	**K022594**	**K973501**
	Gerber DoubleElectric Breast Pump	**Medela Pump-in-Style**	**Playtex Breast Pump**	**Ameda Egnell Purely Yours**
Intended Use:	Express milk	Express milk	Express milk	Express milk
Power Source:	DC	DC	DC	DC
Pump Style:	Diaphragm	Diaphragm	Reciprocating Piston	Reciprocating Piston
Single/double Pumping:	Both	Both	Both	Both
Adjustable Suction Levels:	Yes	Yes	Yes	Yes
Cycle Speed:	Fixed	Variable	Variable	Variable
Overflow Protection:	No	No	Yes	Yes
Highest Vacuum Setting – (mmHg):	240	250	229	170
Lowest Vacuum Setting	0	0	64	31
Active Breast Massage:	Yes	No	Yes	No
Software (microchip)	Yes	Yes	Yes	Yes

Discussion of Non-clinical Tests:
Bench testing of the device has demonstrated that the Gerber Double Electric Breast pump meets established requirements when used in the manner and environment specified in product labeling.

Discussion of clinical tests performed:
No clinical tests have been conducted on this device.

Conclusion:
The Gerber Double Electric Breast Pump is safe and effective for its intended use of milk expression and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2004

Gerber Products Company
% Ms. Chantel Carson
Manager
Underwriters Laboratories, Inc.
Northbrook Division
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K043098
Trade/Device Name: Gerber Double Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: November 24, 2004
Received: November 30, 2004

Dear Ms. Carson:

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 (Premarket Approval), 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K 043098 (To be assigned)

Device Name: Gerber Double Electric Breast Pump

Indications for Use: **An electrically powered breast pump with adjustable vacuum and massage settings and 2 funnels for expressing milk from the breasts of a lactating woman.**

Prescription Use __ **or** **Over-the-counter use** XX
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043098