JAN 1 0 2003

Name of Company: Limerick Inc.
Premarket Notification – 510(k)
Name of Devise: Portable Electric Breast Pump Model 1002

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510(K) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K021739

1. **Submitter's Identification:**

   Limerick Inc.
   903 North San Fernando Blvd., Suite 5
   Burbank, California 91504

   Date Summary Prepared: April 25, 20002

2. **Name of the Device:**

   Portable Electric Breast Pump Model 1002

3. **Predicate Devices Information:**

   Medela Pump In Style Breast Pump (510 (k) not known)
   Ameda Egnell Expresse and Premier Powered Breast pump K973501

4. **Device Description:**

   This portable electric breast pump model 1002 is powered by a variable speed DC motor that drives a diaphragm pump. The diaphragm pump creates the negative pressure required to extract breast milk. This pump has variable speed cycling rates, which is controlled by a knob located on the control panel. The breast pump is capable of providing multiple vacuum levels, which are user selectable by use of a knob located on the front panel. A maximum vacuum of 250-mm Hg. is applied to one or both breast through a disposable filter that is connected by way of flexible tubing to the breast cup(s).

   It can be operated by use of either an AC/DC wall converter or a 12-Volt battery.

   All materials used in the manufacturing of this device that has contact with food or human tissue meet requirement of the FDA and international regulations concerning food contact and/or biocompatability.

5. **Intended Use:**

The intended use of the electrically powered (diaphragm-type) suction device is to express milk from the breast.

6. **Comparison to Predicate Devices:**

Table of Comparison to Legally Marketed Device:

The following is a comparison chart outlining differences and similarities between Limerick Portable Electric Breast Pump Model 1002, Medela Pump In Style, the Expresse and Premier.:

	Proposed Device	**Predicate Devices**		
Characteristics	**Limerick Portable Electric Breast Pump Model 1002**	**Medela Pump In Style-K unknown**	**Ameda/Egnell Expresse K973501**	**Ameda/Egnell Premier K973501**
Intended Use	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160
Suction Levels	20-240 mm Hg.	80-240 mm Hg.	<100-265mbar	<100-265mbar
Suction Cycle	20-50 cycles per minute	48 per minute	30-60 cycles per minute	30-60 cycles per minute
Filter between kit and pump	a) yes	a) No	a) No	a) No
Power Supply	b) rechargeable NiMH battery c) AC adapter d) 12 V adapter for use in motor vehicle	b) rechargeable battery c) AC adapter d) 12 V adapter for use in motor vehicle	b) rechargeable NiCd batteries c) 5 AA alkaline Batteries d) AC Adapter e) 12V adapter for use in motor vehicle	b) rechargeable NiCd batteries c) 5 AA alkaline batteries d) AC adapter e) 12V adapter for use in a motor vehicle
Cycle/Suction Control mechanism	Mechanical cycling suction regulator	Mechanical cycling suction regulator	Microprocessor	Microprocessor
Weight	5.5 pounds	7 pounds	1.1 pounds	1.1 pounds

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7. Conclusions:

Limerick Portable Electric Breast Pump Model 1002 has the same intended use, similar design and technology as the Medela Pump In Style, Expresse and Premier. As our comparison chart indicates, as well as our testing data, Limerick Portable Electric Breast Pump Model 1002 raises no new questions of safety or effectiveness. Thus, when compared to the predicated device, Limerick Portable Electric Breast Pump Model 1002 does not incorporate any significant changes in intended use, method or operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2003

Ms. Patricia A. Kelly
President
Limerick
903 N. San Fernando Blvd.
Suite 5
BURBANK CA 91504-4327

Re: K021739
Trade/Device Name: Limerick's Portable Electric Breast Pump, Model 1002
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: September 16, 2002
Received: November 15, 2002

Dear Ms. Kelly:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Premarket Notification – 510(k)
Name of Devise: Portable Electric Breast Pump model 1002

EXHIBIT B

INDICATIONS FOR USE

510(K) Number: K021739

Device Name: Portable Electric Breast Pump model 1002

Indication for Use: The intended use of the electrically powered (diaphragm-type) suction device is to express milk from the breast of lactating women.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **or** **Over-the-Counter Use** ___X___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021739