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Hollister

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Ameda Egnell Powered Breast Pumps
Expresse and Premier

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor
AMEDA AG
Medizin-Technik
Bösch 106
CH-6331 Hünenberg
Switzerland

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847)680-2849
Fax: (847)918-3860

Date Summary Prepared - September 12, 1997

2. Name of Device:

Expresse and Premier Powered Breast Pumps

3. Name of Predicate Device(s)

- The Medela Lactina Breast Pump by Medela, K875300, April 6, 1988
- The Medela Pump In Style Breast Pump (not known)
- Egnell Elite Breast Pump by Ameda/Egnell, K950531, September 22, 1995

4. Description of Device

The Expresse and Premier powered breast pumps are intended to express the mother's milk of a nursing woman. The pumping can be performed on one breast or both breasts at the same time. A control knob adjusts the suction strength (vacuum) to one of 8 settings between <100 and 360 mbar. Another control knob adjusts the suction rhythm (cycle) to one of 4 settings from 30 to 60 cycles per minute.

The difference between the Premier and Expresse are the special bottle holders on the Expresse for using Freezer bags. All other features are substantially equivalent (Software, size, suction capacity, control knobs, weight, noise level and power supply.)

5. Statement of Intended Use

The Battery Breast Pumps, Expresse and Premier, are intended to express and collect the mother's milk from the breasts of a nursing woman, for the purpose of feeding the collected milk to a baby.

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K973501

P2/2

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6. Statement of Technological Characteristics of the Device

The Expresse and Premier Powered Breast Pumps are substantially equivalent to other powered breast pumps that are in commercial distribution. A chart showing the similarities and differences of the proposed powered breast pumps and the predicate powered breast pumps follows:

	Proposed devices		**Predicate Devices**		
Characteristics	**Expresse**	**Premier**	**Egnell Elite K950531**	**Medela Lactina Select K875300**	**Medela Pump in Style**
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	as described in 21 CFR 884.5160
Suction Levels Single pumping Double Pumping	 <100-360 mbar <100-265 mbar	 <100-360 mbar <100-265 mbar	 0-360 mbar 0-360 mbar	80-240 mmHg	80-240 mm Hg
Suction Cycles	30-60 cycles per minute	30-60 cycles per minute	30-60 cycles per minute	42-60 cycles per minute	48 per minute
Power Supply	a) rechargeable NiCd batteries b) 6 AA alkaline batteries c)AC adapter d) 12 V adapter for use in a motor vehicle	a) rechargeable NiCd batteries b) 6 AA alkaline batteries c)AC adapter d) 12 V adapter for use in a motor vehicle	a) rechargeable NiCd battery b) AC power cord c) 12 V adapter for use in motor vehicle	a) rechargeable battery b) AC adapter c) 12 V adapter for use in a motor vehicle	a) rechargeable battery b) AC adapter c) 12 V adapter for use in a motor vehicle
Cycling/Suction control mechanism	Microprocessor	Microprocessor	Microprocessor	Mechanical cycling suction regulator	Mechanical cycling suction regulator
Breast pumping option	Single or double pumping	Single or double pumping	Single or double pumping	Single or double pumping	Single or double pumping
Weight	1.1 pounds	1.1 pounds	6.5 pounds	5 pounds	7 pounds

7. Conclusion

Based on the information presented above it is concluded that the proposed Expresse and Premier Powered Breast Pumps are safe and effective for their intended use and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister, Inc.
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Re: K973501
Ameda Egnell Powered Breast Pumps,
Lactaline Personal (Expresse and Premier)
Dated: September 12, 1997
Received: September 16, 1997
Regulatory Class: II
21 CFR §884.5160/Product Code: 85 HGX

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Dear Mr. Tokarz:

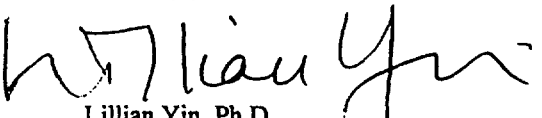
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ameda Egnell Powered Breast Pumps, Lactaline Personal (Premier and Expresse)

b. Statement of Intended Use

510(k) Number (if Known): K973501
Device Name: Ameda Egnell Powered Breast Pumps, Lactaline Personal (Premier/Expresse)

Intended Use:

The Lactaline Personal Powered Breast Pumps (Premier/Expresse) are intended to express and collect the mother's milk of a nursing woman for the purpose of feeding the collected milk to a baby.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-the-Counter-Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Robert P Sullivan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973501