EXHIBIT #1
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SEP 18 1997

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: K971543 .

1. **Submitter's Identification:**

KaWeCo GmbH
Gerlinger Str. 36-38
71254, Ditzingen
Germany

Date Summary Prepared: April 24, 1997

2. **Name of the Device:**

Luxmatic 12-15 ISC Portable Electric Breast Pump

3. **Predicate Device Information:**

K#850705, White River Portable Electric Breast Pump, White River, Division of Natural Technologies, Inc.

4. **Device Description:**

The Luxmatic 12-15 ISC Portable Electric Breast Pump (suction device with a compressor unit) contains a diaphragm-type pump with a vacuum regulator (between 150mm Hg and 220mm Hg) which includes a soft silicone tube and plastic tubing. An accessory kit includes overflow safety bottles, plastic breast shields and a collection cup. The device is battery and line-powered for 12V DC by a transformer or utilizes a 12V battery pack. The device is controlled by an electric sensor with intermittent suction at approximately 30-45 cycles.

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The overflow bottle contains an optical sensor, with an automatic shut off. The motor stops when liquid is sucked into the overflow. The pump can be used with Single Breast Pump Kit #281100 or Double Breast Pump Kit #281102. Dimensions are 7 X 12 X 7 inches and the weight is 4.5 lbs.

Suction is controlled by the pump automatically. It will automatically be released when the adjusted vacuum is reached. An electronic sensor is built-in for automatic motor shut off: If milk flows into the overflow bottle, the motor stops automatically at once and the inside valves from the pump cannot be damaged through the milk. A bacterial filter may be used between the overflow bottle and the pump to prevent cross infection when more than one patient is using the pump. Bacterial filters should be changed regularly.

5. **Intended Use:**

The intended use of this 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 the Luxmatic 12-15 ISC Portable Electric Breast Pump and the White River Portable Electric Breast Pumps:

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PARAMETER	LUXMATIC	WHITE RIVER (K#850705)
Pump Type	Diaphragm	Same
Vacuum Control Cycle	Yes	Same
Adjustable Suction Range	150-220 mm Hg	Not Available
Vacuum Gauge	Yes	Same
Bacteria Filter	Yes	Not Available
Overflow Bottle	Yes	Same
Overflow Shutoff	Yes	Same
Collection Bottles	Yes	Same
Single Patient Use	Yes	Yes
Indications for Use	Same	Same
Weight	4.5 lbs.	10 lbs.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

a) Testing information demonstrating safety and effectiveness of the Luxmatic 12-15 ISC Portable Electric Breast Pump in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlined Electrical, Mechanical and Environmental Performance Requirements.

Testing was conducted on the Luxmatic 12-15 ISC Portable Electric Breast Pump per IEC-601-1-2 (1993) (electrical isolation) and IEC 601-1-1-2 (1993). Testing met TÜV GS Germany requirements. The breastpumps were manufactured in series production and checked with TÜV GS approved

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samples.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards.

b) Patient-contacting material includes both skin contacted material (breastcups) and milk contacting materials. 21 CFR Parts 176, 177 and 178 were reviewed in order to ascertain materials approved for food contact. Materials are approved for food contact.

8. **Discussion of Clinical Tests Performed:**

Non-Applicable

9. **Conclusions:**

The Luxmatic 12-15 ISC Portable Electric Breast Pump has the same intended use, similar design and technology as the White River Portable Electric Breast Pump. As our comparison chart indicates, as well as our testing data, the Luxmatic 12-15 ISC Portable Electric Breast Pump raises no new questions of safety or effectiveness. Thus, when compared to the predicate device, the Luxmatic 12-15 ISC Portable Electric Breast Pump does not incorporate any significant changes in intended use, method of 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

KaWe Co. GmbH
c/o Ms. Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

SEP 18 1997

Re: K971543
Luxmatic 12-15 ISC Portable Electric Breast Pump
Dated: July 31, 1997
Received: August 11, 1997
Regulatory class: II
21 CFR §884.5760/Product code: 85 HGX

Dear Ms. Goldstein-Falk:

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

EXHIBIT B
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510(k) Number (if known): K971543

Device Name: Luxmatic 12-15 ISC Portable Electric Breast Pump

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971543

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)