K092783

Section 5: 510(k) Summary

OCT 22 2009

The following information is provided as required by 21 CFR § 807.87 for ENKO Ltd.'s premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the DEBP is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

Applicant: ENKO Ltd.
10006 sokak, No:64
A.O.S.B. Cigli - Izmir 35620
TURKIYE
Tel: 0090 232 3767806
Fax: 0090 232 3767792
www.enkoelektronik.com
Attn: Sinan Kazazoglu

Contact: Calley Herzog
Biologics Consulting Group, Inc.
13417 Quivas St.
Westminster, CO 80234
Ph. 720-883-3633
Fax. 720-293-0014

Date of Submission: **07/01/2009**

Proprietary Name: DEBP

Common Name: Powered Breast Pump

Regulatory Class: Class II

Product Codes: HGX

Predicate Device(s): Medela swing Breastpump, By Medela Inc. (K053052) & Hollister Inc. Expresse and Premier Powered Breast Pump (Lactaline Personal) (K973501)

Device Description: The Double Electric Breast Pump (DEBP) is a powered breast pump. The pumping can be performed on one breast or on both breasts at the same time. The Lansinoh

DEBP can be powered by 6 AA batteries or an AC adaptor provided with the pump. The pumping system consists of a diaphragm-type vacuum pump which is driven by a microcontroller controlled DC electric motor. The user interface consists of a front panel keypad and LCD display. The user is able to control cycle speed and vacuum level. The Lansinoh DEBP is capable of providing vacuum levels from 50 to 250 mmHg, with cycling rates up to 1.85 cycles per second.

Intended Use: The DEBP is intended to express and collect the mother's milk of a nursing woman for the purpose of feeding the collected milk to a baby.

Performance Testing: Suction curves are provided to illustrate the performance of the DEBP. Additionally a backflow test was conducted to ensure satisfactory performance of the pump in the unlikely event that milk were to backflow into the pump unit.

The DEBP will be tested to meet:

- IEC 60601-1, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-2:2007, "Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility."

Substantial Equivalence: The Lansinoh DEBP is substantially equivalent to the predicate devices in intended use, technological characteristics and device design. The table below provides a comparison of the DEBP to the predicate devices.

	New Device	**Predicate Device**	**Predicate Device**
Manufacturer	ENKO Ltd.	Ameda/Hollister	Medela
Device Name	**DEBP**	**Expresse & Premeier Breast Pumps**	**Medela Swing**
510(k) #	not yet assigned	K973501	K053052
Intended Use	The DEBP is intended to express and collect the mother's milk of a nursing woman for the purpose of feeding the collected milk to a baby.	The Lactaline Personal Breast Pumps 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.	The Swing Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.
Pumping Suction	50 – 250 mmHg	<100 - 265 mbar (<75 – 199 mmHg)	0 - 250 mmHg

Stimulation/Let Down Phase			
Suction Levels	50 – 150 mmHg	n/a	0 - 250 mmHg
Cycles per Second	1.85 (fixed)	n/a	up to 2.17
Expression Phase			
Suction Levels	50 – 250 mmHg	<100 - 360 mbar	0 - 250 mmHg
Cycles per Second	0.51 – 1.0	0.5 – 1.0	up to 2.17
Suction Settings	8	3	11
Power Supply	a) 6 AA alkaline batteries b) AC Adapter	a) rechargeable NiCd batteries b) 6 AA alkaline batteries c) AC Adapter d) 12 V adapter for use in motor vehicle	AC Adapter
Pumping Option	Single or Double	Single or Double	Single
Back Flow Protection	Yes	Yes	No
Let Down Function	Yes	No	Yes
Cycling/Suction Control Mechanism	Microcontroller	Microprocessor	Microprocessor

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

OCT 22 2009

ENKO Ltd.
c/o Mr. Ned Devine
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K092783
Trade/Device Name: DEBP
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: October 5, 2009
Received: October 7, 2009

Dear Mr. Devine:

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); 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: ~~To be assigned~~ K092783

Device Name: DEBP

Indications for Use:

The DEBP is intended to express and collect the mother's milk of a nursing woman for the purpose of feeding the collected milk to a baby.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__

(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K092783