K121478
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510(k) Summary
Revised April 4, 2013

APR 5 2013

Submitted by: MAPA GmbH, Industriestrasse 21-25, 27404 Zeven, Germany

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Product Name: NUK Expressive Double Electric Breast Pump

Common Name: Electric Breast Pump

Classification: Breast Pump, HGX, 21 CFR 884.5160

Predicate Device: K973501 - Ameda Egnell Powered Breast Pumps (Expresse and Premier), Purely Yours

Description of Device:
The NUK Expressive Double Electric Breast Pump is intended to express milk from the breasts. It is intended for use by a single user. This is accomplished by an electrical pump system generating a suck and release vacuum pattern. The suction strength is adjustable. The cycles per minute are adjustable. The electrical pumping unit of the device is connected to the breast shields via silicone tubing. The breast shield and screw housing is equipped with a flap valve separating the breast shield from the NUK breast milk container. The system is assembled in an airtight way to ensure that the system can build up vacuum when the breast shield is connected to the breast. The milk will flow through the flap back flow valve into the bottle. A voltage adaptor is provided with the device.

Indication for Use.
The NUK Expressive Double Electric Breast Pump is intended to express milk from the breasts. It is intended for use by a single user.

Comparison with Predicate Devices:
The submission device and the predicate device have substantially equivalent intended use and technological specifications.

	Predicate Device	**Subject Device**
	Ameda Egnell Powered Breast Pumps (Expresse and Premier)	**NUK Expressive Double Electric Breast Pump**
510(k) Number	K973501	K121478
FDA classification	21 CFR 884.5160	21 CFR 884.5160
Classification Code	HGX	HGX
Indication for 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.	The NUK Expressive Double Electric Breast Pump is intended to express milk from the breasts. It is intended for use by a single user.
Intended Users	Lactating women	Lactating women
Available over the counter	Yes	Yes
Portable	Yes	Yes
Vacuum range	adjustable, <100 to 360 mbar	adjustable, <100 to 360 mbar
Suction cycles	30-60 cycles per minute	30-90 cycles per minute
Power supply	AC adaptor, batteries, car adaptor	AC adaptor
Breast pumping option	Single or double pumping	Single or double pumping
Biocompatibility of materials with tissue contact	Not specified in device labeling	ISO 10993 compliant
Electrical Safety	UL File Number E189700 CSA File Number LR76525	IEC 60601-1 and IEC 60601-1-2 compliant. UL File Number E339441 for Voltage Adapter

Performance:
The NUK device verification testing under the company's Design Control Process has confirmed the device's conformance with specifications. Suction pressure was tested and recorded to verify that the NUK Expressive Double Electric Breast Pump was equivalent to the predicate device using both single and double pumping options. All tissue contact components were tested for biocompatibility according to ISO 10993. The device was also tested for electrical safety testing according to IEC 60601-1. The specifications do not include any significant differences from those of the predicates.

Conclusion:
This submission demonstrates that the NUK Expressive Double Electric Breast Pump is substantially equivalent to the predicate device. It provides evidence that shows the NUK device fits the same classification code definition as the predicate device; the technology for the pump is the same for both devices; the intended users are the same; and performance characteristics such as the vacuum range and suction cycles of both devices are similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

NUK USA LLC
% Mr. Mark Wozniak
Quality Engineer
MAPA GmbH
728 Booster Blvd.
REEDSBURG WI 53959

Re: K121478
Trade/Device Name: NUK® Expressive™ Double Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: March 25, 2013
Received: March 28, 2013

Dear Mr. Wozniak:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX A – Indications for Use

510(k) Number (if known): K121478

Device Name: NUK® Expressive™ Double Electric Breast Pump

Indications for Use:

The NUK Expressive Double Electric Breast Pump is intended to express milk from the breasts. It is intended for use by a single user.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121478