K101157 - NUK Breast Pump - Mapa GmbH

SEP 17 2010

510(k) Summary
Prepared August 12, 2010

Submitted by:	MAPA GmbH Industriestrasse 21-25 Zeven, GERMANY 27404
Contact Person:	Reinhold Jaeger-Waldau Telephone: 049-4281-730-420 e-mail: reinhold.jaeger-waldau@mapa.de

Product Name:	NUK Easy-Flow Single Electric Breast Pump
Common Name:	Electric Breast Pump
Classification:	Breast Pump, HGX, 21CFR 884.5160
Predicate Device:	miPump Single Electric Breast Pump

Description of Device:

The NUK® Easy-Flow™ Single Electric Breast Pump is intended. for use to express milk from the breast by a single use. This is accomplished by an electrical diaphragm pump generating a suck and release vacuum pattern. The suction strength is adjustable. The pumping device is sealed via a connection ring to a breast shield equipped with a valve separating the breast shield from the bottle.

Intended Use:

The NUK® Easy-Flow™ Single Electric Breast Pump is intended. for use to express milk from the breast by a single user.

Comparison with Predicate Devices:

The submission device and the predicate device have substantially equivalent intended use and technological specifications.

K101157 - NUK Breast Pump - Mapa GmbH

	Predicate Device	Subject Device
	miPump Electric Breast Pump by Learning Curve K082802	**NUK Easy-Flow Electric Breast Pump MAPA GmbH**
FDA classification	21 CFR 884.5160	21 CFR 884.5160
Classification Code	HGZ	HGZ
Indication for Use	Powered breast pump to express milk from the breast	The NUK breast pump is intended for use to express milk from the breast of a single user
Intended Users	Lactating women	Lactating women
Available over the counter	Yes	Yes
Portable	Yes	Yes
Vacuum range	Not specified in device labeling	Maximum 250mmHg
Suction mode	adjustable	Adjustable
Type of pump	Electric/Battery	Electric/Battery
Closed System	Yes	Yes
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Electrical Safety	Not specified in device labeling	ISO 60601-1 compliant

Performance:
The NUK device verification testing under the company's Design Control Process has confirmed the device's conformance with specifications. The specifications do not include any significant differences from those of the predicate. Additional performance testing was completed for biocompatibility and electrical safety to recognized standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Sheila W. Pickering, Ph.D.
Consultant
Mapa GmbH
2081 Longden Circle
LOS ALTOS CA 94024

SEP 17 2010

Re: K101157
Trade Name: NUK Easy-Flow Single Electric Breast Pump
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: August 16, 2010
Received: August 24, 2010

Dear Dr. Pickering:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101157

K101157 - NUK Breast Pump - Mapa GmbH

SEP 17 2010

510(k) Number (if known): K101157

Device Name: NUK Easy-Flow Single Electric Breast Pump

Indications For Use:

"The NUK® Easy-Flow™ Single Electric Breast Pump is intended. for use to express milk from the breast by a single user."

Prescription Use_____ OR Over-The-Counter Use ____X____
(Per 21CFR 801)

(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 K101157