Uzinmedicare Co.
503-2,Chang-Ri, Namsa-Myeon,
Yongin-Si, Kyeonggi-Do 449-885, Korea
Tel.82-31-322-0132/Fax.82-31-322-4292

510(k) SUMMARY of Safety and Effectiveness

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

AUG 13 2010

1. Submitter's Information

UZINMEDICARE CO.

503-2, Chang-Ri, Namsa-Myeon, Yongin, Kyeonggi-Do, Korea, Zip:449-885

Phone : +82-31-322-0132

2. Contact Name

Name: Yong J. Choi

Title : Manager

Address: 503-2, Chang-Ri, Namsa-Myeon, Yongin, Kyeonggi-Do, Korea, Zip 449-885

Phone No.: +82-10- 5069-7155

Fax No.: +82- 31- 322- 4292

E-Mail: choiyyjj@yahoo.com

Contact person in U.S

Name: DANIEL MIN

Address: 904-274th Way SESAMMAMISH, WA 98075, USA

Phone No.:1- 206-510-8006

Fax No.: 1-428-369-8795

E-Mail: wwjdksn@hotmail.com

3. Device Identification

Proprietary Name:	Spectra Series Breast Pump
Common/Usual Name:	Powered Breast Pump
Classification Name:	Powered Breast Pump per 21 CFR § 884.5160
Product Code:	HGX

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4. Classification of Device

FDA has classified the predicate devices(K061013, K950750, K973501) as class Ⅱ, CFR § 884.5160. It is our understanding that the powered breast pump fall under the same classification, Sec. § 884.5160 as the predicate devices.

5. Reason for 510(k) Submission

Initial Product Introduction is the reason for submitting the 510(k).

6. Identification of legally marketed predicate device

The subject device is deemed to be substantially equivalent to those following devices manufactured and currently available in commercial distribution.

	Uzinmedicare Spectra Series	**Playtex Embrace Petite Breast Pump**	**Medela Lactina Plus**	**Ameda Purely Yours**
510(k) Number	N/A	K061013	K950750	K973501
Intended Use	To Express Milk	To Express Milk	To Express Milk	To Express Milk
Power Source	AC Power Supply	DC Power Supply	AC Power Supply	DC Power Supply or 6 AA Batteries
Pump Type	Piston	Piston	Piston	Piston
Single or Double Pumping	Both	Both	Both	Both
Adjustable Suction Levels	Yes	Yes	Yes	Yes
Adjustable Cycle Speed	No	No	No	Yes
Overflow Protection	Yes	Yes	No	Yes
Highest Vacuum Setting(mmHg)	400 Less than	214	240	163
Lowest Vacuum Setting(mmHg)	150	72	100	21
Range of Cycle Speeds(Cycles/min)	46-47	45	66-41	67-29
Weight (Kg)	2.1	-	2.4	-

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7. Description of Device

The Spectra Series Breast Pump is operated by AC motor, The device's motor drives a Piston pump, creating a vacuum to express breast milk. Passing through an air tubing to breast shield, the vacuum is used to comfortably draw out the breast milk.
This device operates with power ON at the same time. Also, vacuum regulate operates, and I adjust a vacuum. ON, OFF of a device means opening of absorption and end.

Regular this which is international or foods of FDA shall obey it to safe sanitary rules etc. related to contacts of mother's milk that I faced it to things come in contact on matter or human chest etc.

8. Indications for Use

The Spectra electric breast pump is intended to express breast milk from the breast of lactating woman.

9. Discussion of Non Clinical Tests

All testing of this subject device has demonstrated that the Spectra Series breast pump meets established requirements when used in the manner and environment specified in product labeling.

10. Conclusion

The Spectra Series Breast Pump has the same intended use and similar technological characteristics as the predicate devices. Thus, we are claiming that the Spectra Series Breast Pump is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Yong J. Choi
Manager
Uzinmedicare Co.
503-2, Chang-Ri, Namsa-Myeon
Yongin-Si, Kyeonggi-Do 449-885, KOREA

AUG 13 2010

Re: K093145
Trade Name: Spectra Series Breast Pump
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: May 20, 2010
Received: May 21, 2010

Dear Mr. Choi:

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.

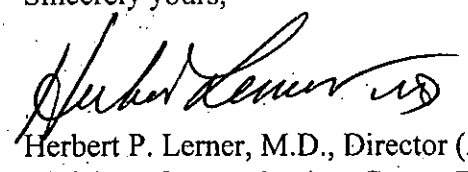
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K093145

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Indications for Use

510(k) Number (if known): K093145

AUG 13 2010

Device Name: Spectra Series Breast Pump

Indications for Use:

The Spectra electric breast pump is Single user product and intended to express breast milk from the breast of lactating woman.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use √ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093145