DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 15, 2016

Uzinmedicare Co.
% Ho Dong Yang
CEO
Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul 135-768
Republic of Korea

Re: K150476
Trade/Device Name: Spectra S1 Plus and Spectra S2 Plus
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: March 9, 2016
Received: March 9, 2016

Dear Ho Dong Yang,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150476

Device Name
Spectra S1 Plus and Spectra S2 Plus

Indications for Use *(Describe)*
The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K150476

In accordance with the requirements of 21 CFR §807.92, the following summary is provided:

SUBMITTER INFORMATION:

UZINMEDICARE CO
Room 105, Joongang Induspia V, Sagimakgolo 137, Jungwon-gu, Seoungnam-Si, Gyeonggi-do, 13202, South Korea

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SECONDARY CONTACT PERSON:

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Davie, FL 33317
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E-mail: hprn@aol.com

DATE SUMMARY PREPARED:

March 21, 2016

DEVICE INFORMATION:

Trade Name(s):	Spectra S1 Plus and Spectra S2 Plus
Classification Name:	Powered breast pump
Regulation:	884.5160
Product Code:	HGX

PREDICATE DEVICE INFORMATION:

Trade Name(s):	PJ's Comfort®
Classification Name:	Powered breast pump
Regulation:	884.5160
Product Code:	HGX

DEVICE DESCRIPTION:
The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women. Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time.

The user employs buttons to switch from massage mode to expression mode and to control the vacuum and cycle levels within those modes. Massage mode consists of 5 suction levels and 1 cycling speed option, while expression mode has 12 suction levels and 5 cycle speed levels. The Spectra S1 Plus and Spectra S2 Plus are capable of providing vacuum levels from 50-280 mmHg with cycling rates up to 70 cycles per minute. The Spectra S1 Plus is powered by a 12V DC adaptor or rechargeable lithium battery. The Spectra S2 Plus is powered only by a 12V DC adaptor.

INDICATIONS FOR USE STATEMENT:
The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

COMPARISON TO PREDICATE DEVICE:
The Spectra S1 Plus and Spectra S2 Plus breast pumps have the same intended use and the same technological characteristics as the Limerick PJ Comfort® (K051926). The general device characteristics and key specifications of the Spectra S1 Plus and Spectra S2 Plus breast pumps and its predicate device are summarized in the following table:

	Subject Device (K150476)	**Predicate Device (K051926)**
GENERAL DEVICE CHARACTERISTICS		
Product Name	Spectra S1 Plus and Spectra S2 Plus	PJ's Comfort
Manufacturer	Uzinmedicare Co.	Limerick, Inc.
Product Code	HGX	HGX
Regulation No.	21 CFR 884.5160	21 CFR 884.5160
Class	Class II	Class II
Patient Population	Breastfeeding women	Breastfeeding women
Indications for Use	The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The PJ's Comfort breast pump is an electrically powered (diaphragm type) suction device intended to express and collect milk from the breasts of lactating women.
SPECIFICATIONS		
Pump Type	Diaphragm	Diaphragm
Pump Options	Single or Double	Single or Double
Suction Levels	Massage Mode: 5 levels Expression Mode: 12 Levels	Unknown
Suction Strength	50-280 mmHg	40-270 mmHg
Cycle Speed	38-70 cycles/min (adjustable)	16-70 cycles/min (adjustable)
Visual Indicator	LCD	Markings and illuminated lights on panel
Power Supply (Conventional Outlet)	AC/DC wall converter	AC/DC wall converter
Power Supply (Battery)	Rechargeable Lithium Ion Battery (only for Spectra S1 Plus)	Rechargeable NiMH Battery
Power Supply (Car Adapter)	N/A	12 V

Back Flow Protection	Yes	Yes

SUMMARY OF NON-CLINICAL TESTS:
The Spectra S1 Plus and Spectra S2 Plus breast pumps comply with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps. The following data were provided to support the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971:2007.
- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2007.
- Safety Testing for use in the home in accordance with IEC 60601-1-11:2010.
- Biocompatibility Tests in accordance with ISO-10993, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).
- Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).
- Medical Device Software – Software Life Cycle Processes in accordance with IEC 62304.

Performance testing was conducted at minimum and maximum vacuum settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications. Tests were conducted for 20 minutes to simulate a typical pumping session. The specifications were met for vacuum level, cycle rate, backflow protection and battery operation time. These results held under conditions of single and double pumping mode and for the Spectra S1 Plus model, of varying power sources (e.g., AC/DC power vs. battery power).

SUMMARY OF CLINICAL TESTS:
Clinical testing was not required to demonstrate the substantial equivalence of the Spectra S1 Plus and Spectra S2 Plus breast pumps to its predicate device.

CONCLUSION:
The differences between the Spectra S1 Plus and Spectra S2 Plus breast pumps and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Based on non-clinical testing, Uzinmedicare Co. concludes that the Spectra S1 Plus and Spectra S2 Plus breast pumps perform as intended and are substantially equivalent to the legally marketed predicate device, Limerick's PJ Comfort.