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

March 15, 2017

Uzinmedicare Company
% Jeffrey Shapiro
Director
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005

Re: K162415
Trade/Device Name: Spectra 9Plus
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: Class II
Product Code: HGX
Dated: February 15, 2017
Received: February 15, 2017

Dear Jeffrey Shapiro:

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,

Benjamin R. Fisher -S

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)*
K162415

Device Name
Spectra 9Plus

Indications for Use *(Describe)*
The Spectra 9Plus is a single user, powered breast pump 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
K162415 Spectra 9plus

In accordance with the requirements of 21 C.F.R. § 807.92, the following summary is provided:

SUBMITTER INFORMATION:
UZINMEDICARE CO
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SECONDARY CONTACT PERSON:
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Davie, FL 33317
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Email: hprn@aol.com

DATE SUMMARY PREPARED: March 14, 2017

DEVICE INFORMATION:

Trade Name(s):	Spectra 9Plus
Common Name:	Breast pump
Classification Name:	Powered breast pump
Regulation:	21 C.F.R. § 884.5160
Product Code:	HGX (pump, breast, powered)
Class:	II

PREDICATE DEVICE INFORMATION:
Double Electric Breast Pump (K092783)

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION:
The Spectra 9Plus is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women. The device is intended to be a single patient reusable device. The device is capable of single and dual pumping.

The Spectra 9Plus is powered by a 9V DC adaptor or rechargeable Lithium ion battery. It is composed of materials commonly found in medical devices such as polypropylene, ABS, and silicone. All milk-contacting components are constructed out of food-grade materials that are compliant with 21 C.F.R. parts 174-179.

The Spectra 9Plus is considered a skin-contacting device with a limited (≤24 hours) contact duration.

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, while expression mode has 10 suction levels and 10 cycling speeds. The Spectra 9Plus is capable of providing vacuum levels from 50-270 mmHg with cycling rates up to 70 cycles per minute.

INTENDED USE:
The Spectra 9Plus is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

The intended use is similar to that of the predicate device.

COMPARISON TO PREDICATE DEVICE:
The Spectra 9Plus pump system has the same intended use and similar technological characteristics as the Double Electric Breast Pump (K092783). The general device characteristics and key specifications of the Spectra 9Plus pump system and the predicate devices are summarized in the following table:

Comparison of Technological Characteristics

Attribute	**Subject Device Spectra 9Plus**	**Predicate Device Double Electric Breast Pump**
510(k) number	K162415	K092783
Single User	Yes	Yes
Provided Non-Sterile	Yes	Yes
Re-usable	Yes	Yes
Direct User Contact	Yes	Yes

Power Source	AC/DC wall converter and Rechargeable Lithium-Ion battery	AC adapter 6 AA alkaline battery
Suction Strength (Expression Mode) (mmHg)	50-270	50-250
Suction Strength (Massage Mode) (mmHg)	50-150	50-150
Adjustable Suction Levels	Yes	Yes
Suction Settings (Expression Mode)	10	8
Suction Settings (Massage Mode)	5	8
Cycle Speed (Expression Mode) (cycles/min)	26-60	30-60
Cycle Speed (Massage Mode)	70	111
Back Flow Protection	Yes	Yes
Single or Double Pumping	Single or Double	Single or Double
Visual Indicator	LCD	LCD with LED backlight
Pump type	Diaphragm	Diaphragm

The differences between the subject device and the predicate device are as follows:

- There are ten (10) vacuum levels for expression mode and five (5) for massage mode in Spectra 9Plus, and eight (8) vacuum levels for both expression and massage mode in the predicate device.
- The cycle speed for Spectra 9plus is 26-60 cycles/ min (expression mode) and 70 cycles/ min (massage mode), and the cycle speed for predicate device is 30-60 cycles/min (expression mode) and 111 cycles/min (massage mode).
- Spectra 9Plus operates via a Li Ion battery and AC/DC wall adapter and the predicate consists of 6 AA alkaline battery and AC adaptor.
- Spectra 9Plus consist of LCD whereas the predicate device consists of LCD with LED backlight.

The differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

SUMMARY OF NON-CLINICAL TESTS:

The Spectra 9Plus breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps.

The following performance data were provided to verify that the subject device met all design specifications and provided support of 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 Al:2012.
- Electromagnetic Compatibility Testing in accordance with lEC 60601-1-2:2007.
- Safety Testing for use in the home in accordance with IEC 60601-1-11:2010.
- Biocompatibility Tests in accordance with lS0-10993, including cytotoxicity (ISO 10993-
- 5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).
- Software Validation - Software Life Cycle Processes in accordance with lEC 62304.
- FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).
- Bench Testing – Vacuum Profile Test, Backflow protection test, and Pump use-life test.

CONCLUSION:
The Spectra 9Plus breast pump is substantially equivalent to the legally marketed predicate device, Double Electric Breast Pump.