November 30, 2018

Uzinmedicare Co.
% Adrienne R. Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps, & McNamara, P.C.
700 Thirteenth N.W., Suite 1200
Washington, D. C. 20005

Re: K181784
Trade/Device Name: Spectra S3 Plus Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: October 30, 2018
Received: October 31, 2018

Dear Adrienne R. Lenz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181784

Device Name
Spectra S3 Plus Breast Pump

Indications for Use *(Describe)*
The Spectra 3 Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra 3 Plus Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K181784

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

DATE PREPARED: November 30, 2018

SUBMITTER:

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

PRIMARY CONTACT PERSON:

Nathan Ahn, Manager
Overseas Department
c/o UZINMEDICARE CO
Room 105, Joongang Induspia V, Sagimakgolo 137, Jungwon-gu, Seoungnam-Si, Gyeonggi-do,
13202, South Korea
Telephone: 82-31-739-5271
Email: shahn@uzinmedical.co.kr

SECONDARY CONTACT PERSON:

Heidi Humphries, RN, BSN, IBCLC
Spectra Baby USA
6851 SW 21ST Court, Suite 1
Davie, FL 33317
Telephone: 954-471-4429
E-mail: hprn@aol.com

DEVICE:

TRADE NAME: Spectra S3 Plus Breast Pump

COMMON/USUAL NAME: Breast Pump

REGULATION NAME: Powered Breast Pump

REGULATION NUMBER: 21 CFR 884.5160

REVIEW PANEL: Obstetrics/Gynecology
PRODUCT CODE: HGX (pump, breast, powered)
REGULATORY CLASS: II

PREDICATE DEVICE(S):

K150476 Spectra S1 Plus Breast Pump
The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION:

The Spectra S3 Plus is a powered breast pump 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 S3 Plus is capable of providing vacuum levels from 50-270 mmHg with cycling rates up to 70 cycles per minute. The Spectra S3 Plus is powered by a 12V DC adaptor or rechargeable lithium battery.

The Spectra S3 Plus breast pump can be used by multiple users. Kits used with the Spectra S3 Plus breast pump, however, are labeled for a single user.

INDICATIONS FOR USE:

The Spectra S3 Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra S3 Plus Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.

PREDICATE DEVICE COMPARISION:

As summarized in the table below, the subject and predicate device have the same intended use – express and collect breast milk. Regarding technological characteristics, the only substantive difference between the subject and predicate device is that the subject device pump is for use by multiple users while the predicate device is for use by a single user. This difference in technological characteristics does not raise different questions of safety or effectiveness.

	Spectra S1 Plus Breast Pump Predicate Device (K150476)	**Spectra S3 Plus Breast Pump**
Patient Population	Breastfeeding women	Breastfeeding women
Indications for Use	The Spectra S1 Plus is a single-user powered breast pump intended to express and collect milk from the breasts of lactating women.	The Spectra S3 Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra S3 Plus Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.
Use Type	Single user	Multi-user and single user
Environment of Use	Home	Hospital, Home
User Interface	LCD display, buttons, night light	LCD display, buttons, night light
Modes of Operation	Massage, Expression	Massage, Expression
Single/Double Pumping	Single or Double	Single or Double
Accessories	Breast shield set, includes • flange (28 mm) • backflow protector • valve • tubing 12V AC Power adapter Bottle Set (bottle, nipple, cap, disk, cover)	Breast shield set, includes • flange (size 20, 24, 28 and 32 mm) • backflow protector • valve • tubing 12V AC Power adapter Bottle Set (bottle, nipple, cap, disk, cover)
Pump Type	Diaphragm	Diaphragm
Suction Levels	12 Levels	12 Levels
Suction Strength	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)

	Spectra S1 Plus Breast Pump Predicate Device (K150476)	**Spectra S3 Plus Breast Pump**
Cycle Speed	38-70 cycles/min (adjustable)	38-70 cycles/min (adjustable)
Power Supply (Conventional Outlet)	AC/DC wall converter Input 100V – 240AC, 50/60Hz, 600mA Output: 12V, 2A	AC/DC wall converter Input 100V – 240AC, 50/60Hz, 600mA Output: 12V, 2A
Power Supply (Battery)	Rechargeable Lithium Ion Battery 11.1V 2000mAh Li-Polymer	Rechargeable Lithium Ion Battery 11.1V 2000mAh Li-Polymer
Back Flow Protection	Yes, provided by silicone membrane backflow protector	Yes, provided by silicone membrane backflow protector
Software	Yes	Yes

SUMMARY OF PERFORMANCE DATA:

SUMMARY OF NON-CLINICAL TESTS:

As stated previously, the only substantive difference between the subject and predicate device is that the subject device is a multi-user pump. Therefore, the subject device leverages performance data conducted on the predicate device. The following new performance tests were conducted on the subject device:

- Vacuum test (battery and AC) to demonstrate that the pump vacuum meets specifications during single pumping and double pumping with battery or AC power (110 VAC, 60 Hz),
- Battery usage test to demonstrate battery usage time,
- Cycle test to demonstrate that the pump cycle rate meets specifications while running on battery or AC power,
- Breast shield size test to demonstrate that the pump meets vacuum specifications with all breast shield sizes,
- Backflow protection test to demonstrate that milk cannot flow through the backflow protector into the breast pump.

In addition, the labeling was updated to reflect use by multiple users and to include

corresponding warnings, precautions, and cleaning instructions.

CONCLUSION:

The performance data demonstrates that the Spectra S3 Plus breast pump is substantially equivalent to the predicate device.