October 11, 2019

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

Re: K191208
Trade/Device Name: Spectra Cashmere
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 11, 2019
Received: September 12, 2019

Dear Adrienne 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon Andrews
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191208

Device Name
Spectra Cashmere

Indications for Use *(Describe)*
The Spectra Cashmere breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra Cashmere 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.

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510(k) Summary

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

SUBMITTER:

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DATE 510(K) SUMMARY WAS PREPARED:

October 11, 2019

DEVICE INFORMATION:

TRADE NAME: Spectra Cashmere

COMMON/USUAL NAME: Breast Pump

REGULATION NUMBER: 21 C.F.R. § 884.5160

CLASSIFICATION NAME: Pump, Breast, Powered
REVIEW PANEL: Obstetrics/Gynecology
PRODUCT CODE: HGX
PRODUCT CODE NAME: Pump, Breast, Powered
REGULATORY CLASS: Class II

PREDICATE DEVICE INFORMATION:

510(k) Number: K181784

Trade/Device Name: Spectra S3 Plus Breast Pump

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

DEVICE DESCRIPTION:

The Spectra Cashmere is a powered breast pump intended to express and collect milk from the breasts of lactating women. Two models are available:

- Model MM010035 is the retail model, which includes the breast pump Part # IMP-0034, double collection kit, ac adapter, and 2 collection bottles.
- MM010035-H is multi-user hospital grade model, which includes the breast pump Part # IMP-0034 and ac adapter only.

The Spectra Cashmere component(s) consist of:

- Spectra Cashmere pump with ABS housing,
- Breast shield set, includes polypropylene flange (size 20, 24, 28 and 32 mm), backflow protector, valve, tubing,
- 12V AC power adapter,
- Bottle set (bottle, nipple, cap, disk, cover).

Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time. The user employs buttons to select one or both sides for pumping, 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 5 cycling speed options, while expression mode has 15 suction levels and 5 cycle speed levels.

The Spectra Cashmere includes a diaphragm pump using two motors, one for each breast, to generate vacuum for breastmilk expression. Backflow protection is provided by the breast pump set's backflow protector. The silicone membrane backflow protector serves as a barrier between the breast shield and collection bottle (user side) and the tubing connected to the pump (pump side) to prevent the introduction of any fluids into the tubing or the pump's housing, thus preventing cross-contamination between users.

The Spectra Cashmere breast pump is capable of providing vacuum levels from 50-270 mmHg with cycling rates up from 38 to 76 cycles per minute. The Spectra Cashmere breast pump is powered by a 12V DC adaptor.

The Spectra Cashmere breast pump is a non-sterile device intended for repeated use by multiple users in a hospital setting. It is also intended for repeated use in the home use by a single user.

Kits used with the Spectra Cashmere are intended for a single user in either the home or hospital environment. The polypropylene breast shields used with the Spectra Cashmere breast pump have direct contact with the user's intact skin. Contact duration is prolonged considering cumulative use of the device.

The Spectra Cashmere breast pump includes software.

INDICATIONS FOR USE:

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

SUBSTANTIAL EQUIVALENCE COMPARISON:

The following table compares the indications for use statements and technological characteristics of the subject and predicate devices.

	Spectra S3 Plus Breast Pump (K181784)	**Spectra Cashmere Breast Pump (K191208)**
Product Name	Spectra S3 Plus	Spectra Cashmere
Patient Population	Breastfeeding women	Breastfeeding women

	Spectra S3 Plus Breast Pump (K181784)	Spectra Cashmere Breast Pump (K191208)
Indications for Use	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.	The Spectra Cashmere Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra Cashmere Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.
Environment of Use	Hospital, Home	Hospital, Home
User Control	Tact switches to control • vacuum setting • cycle speed setting • mode of operation • night light • power (on vs. off)	Touch switches to control • vacuum setting left • vacuum setting right • right/left pump • cycle speed setting • mode of operation/mute • night light • power (on vs. off)
Visual Indicator	LCD display indicates • vacuum setting • cycle speed setting • mode of operation • pump operating time • battery status.	LED display indicates • vacuum setting (each motor) • cycle speed setting • mode of operation • pump operating time • mute
Night Light	LED light with two lighting levels	LED light with two lighting levels
Modes of Operation	Massage, Expression	Massage, Expression

	Spectra S3 Plus Breast Pump (K181784)	Spectra Cashmere Breast Pump (K191208)
Single/Double Pumping	Single or Double	Single or Double
Accessories	Breast shield set, Power adapter, Bottle set	Breast shield set, Power adapter, Bottle set
Cleaning – multi-user pump unit	After every use • Wipe breast pump with a clean, damp cloth.	After every use • Remove and discard all pumping parts/accessories. • Using a biocidal disinfectant, like CaviCide, dampen a clean cloth with the disinfectant and wipe all pump surfaces making sure the liquid doesn't penetrate crevices and any milk stains or spots are removed. Wipe the power cord as well with the disinfectant. Use a cotton swab to thoroughly clean hard to reach places. • Alcohol (70 – 90 %) may also be used as a disinfectant. • Make sure pump is clean and functioning properly before putting it back to use.
Pump Type	Diaphragm	Diaphragm
Suction Levels	12 Levels	15 Levels
Suction Strength	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)
Cycle Levels	1 level for massage and 5 levels for expression	5 levels for massage and 5 levels for expression

	Spectra S3 Plus Breast Pump (K181784)	Spectra Cashmere Breast Pump (K191208)
Cycle Speed	38-70 cycles/min (adjustable)	38-76 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, 500mA Output : 12V, 2A
Power Supply (Battery)	Rechargeable Lithium Ion Battery 11.1V 2000mAh Li-Polymer	No battery
Back Flow Protection	Yes, provided by silicone membrane backflow protector	Yes, provided by silicone membrane backflow protector
Software	Yes	Yes

The Spectra Cashmere breast pump has identical indications for use and uses the same fundamental technology as the legally marketed predicate devices to which substantial equivalency is claimed, the Spectra S3 Plus (K181784). The significant difference between the cleared pump and the Spectra Cashmere is the use of two motors and solenoids to provide independent control of vacuum for each breast. All patient and breast milk contacting materials are identical. The differences in technological characteristics do not raise different questions of safety or effectiveness

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING:

The Spectra Cashmere breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following data were summarized as part of the company's Design Controls process within the Quality Management System in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971: 2007.
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005 standard and IEC 60601-1-2: 2014 (4th edition) standards, respectively.
- Safety testing for use in the home per IEC 60601-1-11: 2010 standard.

- Software verification and validation testing verified each output generated by the software and validated that the software performs in a manner that meets the user needs and intended use. Testing confirmed proper function of the system, display, button controls and settings.
- The Spectra Cashmere breast pump was tested to demonstrate it meets its performance specifications. The testing involved measurement of vacuum and cycles for minimum and maximum settings for both single and double pumping, performance, performance with all breast shield sizes and verification of backflow protection. Tests were conducted for 20 minutes to simulate a typical pumping session. The Spectra Cashmere breast pump performed equivalently to predicate Spectra S3 Plus breast pump in all test cases.

CONCLUSION:

The performance testing demonstrates that the Spectra Cashmere breast pump is substantially equivalent to the predicate device.