January 22, 2020

Uzinmedicare Co.
% Dogyun Im
Senior Researcher
GMS Consulting Co., Ltd.
34, Sangamsan-ro, Mapo-gu, Seoul, Republic of Korea
Seoul-si,Mapo-gu 03909
KOREA, REPUBLIC OF

Re: K191109
Trade/Device Name: Spectra Q
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: April 23, 2019
Received: April 26, 2019

Dear Dogyun Im:

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,

Monica D. Garcia, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastrorRenal, 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)*
K191109

Device Name
Spectra Q

Indications for Use *(Describe)*
The Spectra Q is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Spectra Q is 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 – K191109

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

January 21, 2020

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Uzinmedicare Co.
- Address: 1) Rm 105, Joongang Induspia V, Sagimakgolo 137, Jungwon-gu, Seongnam-Si, Gyeonggi-do, 13202, South Korea

  2) 56 Dongtansandan 5-gil, Dongtan-myeon, Hwaseong-si, Gyeonggi-do, 18487, South Korea
- Contact Name: JISUN LEE
- Telephone No.: 1) +82-31-739-5271

  2) +82-31-375-1076
- Fax No.: 1) +82-31-739-5269

  2) +82-31-375-1079
- Email Address: zsuny@uzinmedical.co.kr

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	Spectra Q
Regulation Name	Powered breast pump
Regulation Number	21 CFR 884. 5160
Common Name	Powered breast pump
Product Code	HGX (Pump, Breast, Powered)
Regulatory Class	Class II

4. Identification of Predicate Device [21 CFR 807.92(a)(3)]

- 510(k) Number: K162415
- Applicant: Uzinmedicare Co.
- Trade/Device Name: Spectra 9Plus

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

5. Description of the Device [21 CFR 807.92(a)(4)]

The Spectra Q breast pump is comprised of a Spectra Q pump, breast shield (20, 24, 28, 32 mm), backflow protector, silicone valve, tubing, bottles (including the nipple, cap, cover, and disk), 2-way connector (for double pumping), and power adapters. The breast pump is provided with one 24 mm and one 28 mm breast shield. Optional components include a small cap converter, assembled with the feeding bottle, the 20 and 32 mm breast shields, and a wide bottle stand.

The Spectra Q breast pump is used by lactating women to express and collect milk from their breasts. The pump is intended for home use by a single user. Pumping with the Spectra Q breast pump can be performed on one breast (single pumping) or on both breasts at the same time (double pumping).

The Spectra Q breast pump allows the user to adjust the vacuum levels. Two suction patterns, massage and expression mode, are pre-programmed with variable vacuum levels and cycle rates (pump speed). The powered breast pump is capable of providing vacuum levels from -50 to -270 mmHg with cycle rates up to 110 cycles per minute. The device is powered by a 6 V AC/DC power adapter or a 5 V USB C type power adapter. Device specification are listed in Section 7 below. The device is provided non-sterile.

The Spectra Q provides the following user features:

- Five LED indicators for vacuum levels
- Four buttons for adjustment of on/off, selection of mode, decrease vacuum, and increase vacuum
- Massage Mode: pumping pattern with lower vacuum levels and higher cycle speeds. The indicator lights are flickering when operating in massage mode.
- Expression Mode: pumping pattern with higher vacuum levels and lower cycle speeds. The indicator lights are solid when operating in expression mode.
- Option of either single or double (dual) breast pumping

6. Indications for use [21 CFR 807.92(a)(5)]

The Spectra Q is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Spectra Q is intended for home use by a single user.

7. Substantial Equivalence Discussion [21 CFR 807.92(a)(6)]

The table below presents comparisons between the subject device (Spectra Q) and the legally marketed predicate device (K162415):

Table 1. Comparison of Spectra Q to Predicate Device

	Spectra Q Breast Pump (Subject Device) K191109	**Spectra 9Plus Breast Pump (Predicate Device) K162415**
Indications for Use	The Spectra Q is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Spectra Q is intended for home use by a single user.	The Spectra 9Plus is a single user, powered breast pump intended to express and collect milk from the breasts of lactating women.
Single user device	Yes	Yes
Intended use environment	Home	Home
Regulation Number	21 CFR 884.5160	21 CFR 884.5160
Product Code	HGX	HGX
Device Class	II	II
Sterility	Not sterile	Not sterile
User Interface and Controls		
User Controls	LED display, buttons for on/off, mode selection, increase/decrease vacuum	LCD Display, buttons for on/off, massage mode, increase/decrease vacuum
Pump Options	Single or Double	Single or Double
Accessories	• Wide breast shield (size 20/24/28/32 mm) • Backflow protector • Silicone valve • Tubing • 2-way connector • 6V AC/CD wall adapter • 5V USB C power adapter • Bottle Set (bottle, nipple, cap, disk, cover)	• Breast Shield • Backflow protector • Valve • Tubing • 9 V AC/DC wall adapter • Bottle • Bottle cover • Bottle cap
Cleaning Method	Breast shield, valve, backflow protector, and bottle set – wash and sanitize daily Tubing – wash and dry if condensation is present in the tubing	Breast shield, valve, backflow protector, and bottle set – wash and sanitize Tubing – wash and dry if condensation is present in the tubing Breast pump body: wipe with damp cloth
Specifications		
Power sources	AC/DC wall adapter (6 V DC) USB C adapter (5 V DC)	AC/DC Converter (9 V DC) Rechargeable Lithium-ion battery
Pump type	Diaphragm	Diaphragm
Suction strength (massage)	50 – 150 mmHg	50 – 150 mmHg
Cycles per minute (massage)	65 – 110	70
Suction levels (massage)	5	5

Suction strength (expression)	130 – 270 mmHg	50 – 270 mmHg
Cycles per minute (expression)	25 – 52	26 – 60
Suction levels (expression)	5	10
Backflow Protection	Yes – connector with silicone membrane to protect against backflow.	Yes – connector with silicone membrane to protect against backflow.

The subject and predicate devices have similar indications for use and the same intended use – expressing milk from the breasts of lactating women. The subject and predicate devices have different technological features. The subject and predicate device have different user interfaces, cycle ranges, suction strength (expression mode), suction levels (expression mode), and power sources. The differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Tests

The Spectra Q complies with voluntary standards for electrical safety, electromagnetic compatibility, and use in the home healthcare environment. The following non-clinical performance data were provided in support of the substantial equivalence determination:

Electrical Safety/Electromagnetic Compatibility

Testing in accordance with the following standards:

- AAMI / ANSI ES60601-1:2005/A1:2012, Medical Electrical Equipment: Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11:2015, Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment2) Software Validation

Software Validation

Software/firmware verification and validation were provided in accordance with the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

Biocompatibility

Biocompatibility evaluation was completed according to the FDA guidance "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," dated June 16, 2016, and concluded that no new testing was required, as all patient-contacting materials are identical to those used in the predicate device (K162415). Milk-contacting components were identified and were compliant with appropriate food-contacting regulations (21 CFR 177.1520).

Bench Performance Testing

Bench performance testing was conducted with internal test protocols to confirm the minimum and maximum vacuum levels of the pump, as well as cycle rate, meets the listed specifications. The specifications were met for all vacuum levels and cycle rates, for single and double pumping with both power sources (AC/DC wall adapter and USB C adapter). Pump use life testing was conducted to demonstrate the device maintains its specifications throughout its use life under all power sources and worst-case cycle parameters.

8. Conclusion [21 CFR 807.92(b)(3)]

The subject and predicate devices have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate the subject device is substantially equivalent to the predicate device.