December 12, 2022

Uzinmedicare Co., Ltd.
℅ Im Dogyun
Senior Researcher
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
Korea, South

Re: K220926
Trade/Device Name: SPECTRA WEARABLE
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: November 2, 2022
Received: November 7, 2022

Dear Im Dogyun:

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 -S

Monica D. Garcia, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K20220926

Device Name
SPECTRA WEARABLE

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

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510(k) Summary – K220926

1. Date Prepared

December 9, 2022

2. Submitter's Information

- Name of Manufacturer: Uzinmedicare Co., Ltd.
- Address: 56, Dongtansandan 5-gil, Hwaseong-si, Gyeonggi-do, Republic of Korea
- Contact Name: JANG dain
- Telephone No.: +82 10-4740-0423
- Email Address: jdi0503@uzinmediar.com
- Registration No.: 3011139154

3. Trade Name, Common Name, Classification

510(k) Number	K220926
Trade Name	SPECTRA WEARABLE
Common Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160
Regulation Name	Powered breast pump
Product Code	HGX (Pump, Breast, Powered)
Regulatory Class	II
510(k) Review Panel	Obstetrics/Gynecology

4. Identification of Predicate Device

510(k) Number	K202037
Trade/Device/Model Name	imani i2
Regulation Number	21 CFR 884. 5160
Classification Product Code	HGX
Device Class	II

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

5. Device Description

The SPECTRA WEARABLE is a powered breast pump that is intended to express and collect milk from the breasts of lactating women. This breast pump is intended for use by a single user and can be used to pump breast milk from a single breast (single pumping). It is designed to work in the user's bra and is battery operated so it can be used hands-free without external power cords. The device is provided non-sterile. The SPECTRA WEARABLE allows the user to adjust the vacuum levels. Two suction patterns, massage and expression mode, are pre-programmed with variable levels and cycle speeds. The subject device is powered by a rechargeable Li-polymer battery (3.7 V, 1500 mAh).

6. Indications for use

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

7. Comparison of Intended Use and Technological Characteristics

The intended use and key technological characteristics of the subject and predicate device are compared in the table below.

Table 1. Comparison of Subject Device to Predicate Devices

	Subject Device	**Predicate Device**	**Comparison**
Product Name	Powered Breast Pump	Powered Breast Pump	N/A
Model Name	SPECTRA WEARABLE	imani i2	N/A
Manufacturer	Uzinmedicare co., Ltd.	imani Co.	N/A
Indications for Use	The Spectra Wearable is a powered breast pump to be used by lactating women to stimulate, express and collect milk from their breasts. The Spectra Wearable is intended for home use by a single user.	The imani i2 breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The imani i2 breast pump is a single user device.	Similar
Single user device	Single user	Single user	Same
Submission Number	K220926	K202037	N/A
Product Code	HGX	HGX	Same
Device Class	II	II	Same
Sterility	Not sterile	Not sterile	Same
User Interface and Controls			
Design	Wearable pump	Wearable pump	Same
Pump Options	Single	Single	Same
Accessories	• Wearable breast pump • Wearable cover • Wearable breast shield • Wearable silicone membrane • Wearable silicone valve • Wearable bottle • Bottle connector • Connector pin • Airtight cap • PP bottle • Nipple • Screw cap • Cover • Adapter	• Breast Funnel (sizes: 25mm and 28 mm [32 mm sold separately]) • Collection Bottle • Valve • Diaphragm Backflow Protector • Connector • Charging cable	Different
Cleaning method	Wash and sanitize	Wash and sanitize	Same
Specifications			
Power sources	Rechargeable Li-Polymer Battery	Rechargeable Li-Polymer Battery	Same

	Subject Device	Predicate Device	Comparison
Suction strength	Expression mode: 100 – 270 mmHg, 5 levels Massage mode: 50 – 130 mmHg, 5 levels	Pumping mode: 80 - 270 mmHg, 5 levels Massage mode: 50 – 150 mmHg, 5 levels	Different
Cycle speed	Pumping mode: 12 – 53 CPM Massage mode: 60 – 100 CPM	Pumping mode: 24 – 55 CPM Massage mode: 65 CPM	Different
Backflow Protection	Yes	Yes	Same

The subject and predicate device have similar indications for use statements and the same intended use – to express and collect milk from lactating women. The subject and predicate device have different technological characteristics, including different accessories, suction strengths, and cycle speeds. However, the differences in technological characteristics do not raise different questions of safety and effectiveness.

8. Non-Clinical Test summary

Non-clinical tests were conducted to verify that the proposed device met all design specification and that they subject device is substantially equivalent to the predicate device. The subject device has been tested as follows:

1) Electromagnetic Compatibility and Electrical Safety

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI ANSI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1: 2005(R)2012 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2016
60601-1-11	IEC	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 environment	60601-1-11 Edition 2.0 2015-01	2016

2) Software Validation

- The software documentation of the subject device was provided in accordance with FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

3) Biocompatibility

- Cytotoxicity per ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

- Sensitization per ISO 10993-10:2010, Biological evaluation of medical devices – Part 10L Tests for irritation and skin sensitization
- Irritation per ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

The results of these tests demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

4) Performance Testing

- Vacuum performance testing, cycle performance testing, and backflow protection 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. The specifications were met for vacuum level, cycle rate, and backflow protection.
- Use life testing was conducted to demonstrate that the device maintains its performance specifications throughout its proposed use-life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

9. Conclusion

The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.