April 6, 2026

Uzinmedicare Co., Ltd.
% Jong-Hyun Kim
CEO
GMSC Co., Ltd
66, Cheongcho-ro, Deogyang-gu, Goyang-si
Gyeonggi-do, 10543
KOREA, SOUTH

Re: K250208
Trade/Device Name: SPECTRA Wearable 2
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 5, 2026
Received: March 5, 2026

Dear Jong-Hyun Kim:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250208

Device Name
SPECTRA Wearable 2

Indications for Use *(Describe)*
The SPECTRA Wearable 2 is a powered breast pump to be used by lactating women to stimulate, express and collect milk from their breasts. The SPECTRA Wearable 2 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.

510(k) Summary – K250208

1. Submitter Information

Applicant:	Uzinmedicare Co., Ltd.
Contact:	Dain Jang
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Email:	jdi0503@uzinmedicare.com
Address:	56, 60 Dongtansandan 5-gil, Hwaseong-si, Gyeonggi-do, Republic of Korea [Zip.18487]
Date Prepared:	April 2, 2026

2. Correspondent Information

Contact:	Jong-Hyun Kim CEO
Firm:	Global Medical Standard Consulting Co. Ltd.
Phone:	+ 82-02-2135-9540
Email:	fda@gmsc.kr

3. Device Information

Device Trade Name:	SPECTRA Wearable 2
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

4. Predicate Device Information

Device Name:	SPECTRA Wearable
510(k) Number:	K220926
Manufacturer:	Uzinmedicare Co., Ltd.

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

5. Device Description

The SPECTRA Wearable 2 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 breast-feeding 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 preprogrammed with variable levels and cycle speeds. The subject device is powered by a rechargeable Li-polymer battery (3.7 V, 1500 mAh).

All milk-contacting components of the device are made of materials that comply with the applicable food-contact regulations specified under 21 CFR Parts 174-179.

6. Indications for Use

The SPECTRA Wearable 2 is a powered breast pump to be used by lactating women to stimulate, express and collect milk from their breasts. The SPECTRA Wearable 2 is intended for home use by a single user.

7. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate and device.

Table 1: Comparator Table for Subject, Predicate Device

	Subject Device	Predicate Device K220926	SE Note
Product Name	Powered Breast Pump	Powered Breast Pump	-
Model Name	SPECTRA Wearable 2	SPECTRA Wearable	-
Manufacturer	Uzinmedicare co., Ltd.	Uzinmedicare co., Ltd.	-
Indications for Use	The SPECTRA Wearable 2 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The SPECTRA Wearable 2 is intended for a single user.	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.	Same
Single user device	Single user	Single user	Same
Submission Number	K250208	K220926	-
Product Code	HGX	HGX	Same
Device Class	II	II	Same
Sterility	Not sterile	Not sterile	Same
Specifications			
Pump Type	Diaphragm	Diaphragm	Same
Design	Wearable pump	Wearable pump	Same
Accessories	• Wearable breast pump • Shield (inner diameter 30 mm) • Milk outlet cap • Silicone O-ring • Silicone Membrane • Backflow protector • silicone valve • Milk collection bottle • Sizing insert set (22, 24, 26 mm) • Storage/Portable pouch • Milk storage bag • Adapter	• 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	Different
Suction Strength	Expression mode: 100 – 270 mmHg, 5 levels Massage mode: 50 – 130 mmHg, 5 levels	Expression mode: 100 – 270 mmHg, 5 levels Massage mode: 50 – 130 mmHg, 5 levels	Same

	Subject Device	Predicate Device K220926	SE Note
Cycle Speed	Pumping mode: 12 – 53 CPM Massage mode: 60 – 100 CPM	Pumping mode: 12 – 53 CPM Massage mode: 60 – 100 CPM	Same
Power sources	Rechargeable Li-Polymer Battery	Rechargeable Li-Polymer Battery	Same
Back Flow Protection	Yes	Yes	Same

The Indications for Use of the subject device and predicate device are completely identical. Both products are single user products, and among the product characteristics, the conditions of pump type, pump option, suction strength, cycle speed, power sources, and back flow protection are all the same. The difference between the two products is the accessories. The functions are the same, but the design is slightly different, and some accessories have been added. These differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications to be considered substantially equivalent to the predicate device.

Biocompatibility

Per the 2023 FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical – Part 1: Evaluation and testing within a risk management process",* the following tests were performed on the direct user contacting device materials:

- Cytotoxicity / ISO 10993-5:2009
- Sensitization / ISO 10993-10:2010
- Irritation / ISO 10993-23:2021

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety

Testing was conducted in accordance with

- IEC 60601-1:2005 + A1:2012 + A2:2020 (3.2 Edition) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015+A1:2020 (2.1 Edition) 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
- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

Electromagnetic Compatibility

Testing was conducted in accordance with

- IEC 60601-1-2:2014 + AMD 1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- IEC TR 60601-4-2:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Software

- Software was evaluated as recommended in the 2023 FDA guidance document, *Content of Premarket Submissions for Software Functions.*

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Life cycle performance testing was conducted to demonstrate that the main device and accessories maintain its specifications throughout its proposed use life.

9. Conclusion

The results of the performance testing described above demonstrate that the SPECTRA Wearable 2 is as safe and effective as the predicate device and supports a determination of substantial equivalence.