June 4, 2026

Uzinmedicare Co., Ltd.
Soyeon Lim
Researcher
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KOREA

Re: K260956
Trade/Device Name: Spectra Platinum Mini
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 22, 2026
Received: March 23, 2026

Dear Soyeon Lim:

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,

VASUDHA C. SHUKLA -S

For
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)*
K260956

Device Name
Spectra Platinum Mini

Indications for Use *(Describe)*
The Spectra Platinum Mini is single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

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.

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510(k) Summary
K260956

1. Submitter Information

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Correspondent Information
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Phone: +82-70-5228-1466
Email: soyeon.lim@uzinmedicare.com

2. Date prepared: June 2, 2026

3. Device Information

Device Trade Name:	Spectra Platinum Mini
Common Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

4. Predicate Device Information

Device Name:	Spectra Platinum
510(k) Number:	K251932
Manufacturer:	Uzinmedicare Co., Ltd.

The Predicate Device has not been subject to a design-related recall.

5. Device Description

The Spectra Platinum Mini is an electrically powered breast pump intended for use by lactating women to stimulate lactation and express breast milk. The device is intended for single-user, home use. Pumping can be performed on one breast (single pumping) or both breasts (dual pumping) at the same time.

The Spectra Platinum Mini operate using an AC adapter (100-240V AC, 50/60Hz, DC 5V) or a rechargeable Li-Polymer battery (3.7V, 2,300mAh).

The Spectra Platinum Mini is comprised of the following components: Main unit, Power adapter, Tubing, Backflow protector, Wide breast shield, Milk bottle, Screw ring, Cap, Sealing cap for milk bottle, Silicone nipple, Silicone valve. The device is provided non-sterile.

The Spectra Platinum Mini supports a single pumping mode in which only one breast is expressed and a dual pumping mode in which both breasts are expressed. The user can switch between Massage Mode and Expression Mode using designated buttons and adjust the vacuum level and cycle speed within each mode.

Spectra Platinum includes the following features:

- Expression can be performed on one breast only (single mode), on both sides simultaneously (dual mode).
- Expression mode: 1-10 level (90-270 mmHg), cycle speeds (21, 22, 30)
- Massage mode: 1-5 level (60-100 mmHg), cycle speeds (100)

The Spectra Platinum Mini operate within these specified parameters.

When the backflow protector is assembled between the pump unit and the wide breast shield, the silicone membrane inside the backflow protector creates a hygienic barrier by preventing air and milk from flowing back into the pump unit. This not only enables safe and hygienic breast pumping, but also protects the pump unit from contamination and potential damage caused by backflow of milk.

6. Indications for Use

The Spectra Platinum Mini is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

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, predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Subject Device	Predicate Device (K251932)
General Device characteristics		
Trade/Model name	Spectra Platinum Mini	Spectra Platinum
Product Code	HGX	HGX
Manufacturer	Uzinmedicare Co., Ltd.	Uzinmedicare Co., Ltd.
Regultation No.	21 CFR 884. 5160	21 CFR 884. 5160
Device Class	II	II
Patient Popualtion	Lactating Women	Lactating Women
Indication for Use	The Spectra Platinum Mini is single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The Spectra Platinum is single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.
Specifications		
Pump Type	Diaphragm	Diaphragm
Pump Options	Single or Double	Single or Double
Suction Levels	Expression Mode: 10 Levels Massage Mode: 5 Levels	Expression Mode: 15 Levels Massage Mode: 5 Levels
Suction Strength	Expression : 90-270 mmHg Massage Mode : 60-100 mmHg	Expression : 90-270 mmHg Massage Mode : 60-100 mmHg
Cycle Speed	Expression : 21-30 cycles/min Massage : 100 cycles/min	Expression : 38-54 cycles/min Massage : 70-105 cycles/min
Visual Indicator	LED	OLED

Power Supply (Conventional Outlet)	AC/DC wall converter -Input: AC 100-240 V, 50/60 Hz -Output: DC 5 V 2 A	AC/DC wall converter -Input: AC 100-240 V, 50/60 Hz -Output: DC12 V 2 A
Power Supply (Battery)	Rechargeable Lithium Ion Battery 3.7 V 2,300 mAh Li-Polymer	Rechargeable Lithium Ion Battery 11.1V 2,000mAh Li-Polymer
Back Flow Protection	Yes	Yes

The indications for use of the subject and predicate devices are identical, and they have the same intended use – the expression and collection of breast milk from lactating women.

There are differences in technological characteristics between the subject and predicate device, including suction levels, cycle speed, and power supply. However, these differences do not raise different questions of safety or effectiveness and can be evaluated through performance testing.

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 user contacting device parts:

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

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

Electrical Safety

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 62133-2:2017Secondary 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 (EMC)

EMC 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.

Software

- Software verification and validation consistent with a basic level of concern was provided per 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/level demonstrated that the devices meet mode/level specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Use-life performance testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.

9. Conclusion

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