February 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: K251423
Trade/Device Name: Spectra S1 Pro; Spectra S2 Pro
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 6, 2026
Received: January 6, 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, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,
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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)*
K251423

Device Name
Spectra S1 Pro; Spectra S2 Pro

Indications for Use *(Describe)*
The Spectra S1 Pro and Spectra S2 Pro are single-user, powered breast pumps 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.

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510(k) Summary – K251423

1. Submitter Information

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2. Correspondent Information

Contact: Jong-Hyun Kim
CEO
Firm: Global Medical Standard Consulting Co. Ltd.
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Email: fda@gmsc.kr

3. Date prepared: February 5, 2026

4. Device Information

Device Name:	Spectra S1 Pro; Spectra S2 Pro
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

5. Predicate Device Information

Device Name:	Spectra S1Plus and Spectra S2 Plus
510(k) Number:	K150476
Manufacturer:	Uzinmedicare Co., Ltd.

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

6. Device Description

The Spectra S1 Pro and Spectra S2 Pro are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women. Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time. The Spectra S1 Pro and Spectra S2 Pro are comprised of the following components: pump unit, adapter, wide breast shield, back-flow protector, tubing, silicone valve, bottle cap, bottle screw, nipple, airtight cap, and PP bottle. The device is provided non-sterile.

The Spectra S1 Pro and Spectra S2 Pro support 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 S1 Pro and Spectra S2 Pro includes the following features:

- Expression can be performed on one breast only (single mode), on both sides simultaneously (dual mode).
- Expression mode: 1-15 level (50-270 mmHg), cycle speeds (38, 42, 46, 50, 52, 58)
- Massage mode: 1-5 level (50-180 mmHg), cycle speeds (70, 80, 90, 100, 105)

The Spectra S1 Pro operates using an AC adapter (100-240V AC, 50/60Hz, DC 12V) or a rechargeable Li-Polymer battery (11.1V, 2000mAh). The Spectra S2 Pro operates using an AC adapter (100-240V AC, 50/60Hz, DC 12V) only.

When the backflow protector is assembled between the pump unit and the breast shield, the silicone membrane inside the backflow protector creates a physical barrier by preventing air and milk from flowing back into the pump unit.

All milk contacting components are compliant with 21 CFR 177.

7. Indications for Use

The Spectra S1 Pro and Spectra S2 Pro are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

8. 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 device.

Table 1: Comparator Table for Subject and Predicate Devices

	Spectra S1 Pro; Spectra S2 Pro K251423 Subject Device	**Spectra S1 Plus; Spectra S2 Plus K150476 Predicate Device**	**Comparison**
Product Name	Spectra S1 Pro; Spectra S2 Pro	Spectra S1 Plus; Spectra S2 Plus	**N/A**
Code	HGX	HGX	Same
Indications for use	The Spectra S1 Pro and Spectra S2 Pro are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	Same
Single User	Yes	Yes	Same
Single/double pump	Single or double	Single or double	Same
Pump Type	Tabletop diaphragm	Tabletop diaphragm	Same
Media separation (backflow protection)	Yes	Yes	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
User Interface	LCD, button controls	LCD, button controls	Similar
Expression pattern	2-Phase	2-Phase	Same
Power supply (with	AC/DC wall converter	AC/DC wall converter	Same

adaptor)	-Input: AC 100-240V, 50/60Hz -Output: DC12V 2A	-Input: AC 100-240V, 50/60Hz -Output: DC12V 2A	
Power supply (internally powered)	S1 Pro: Rechargeable Lithium Ion Battery 11.1V 2,000mAh Li-Polymer	S1 Plus: Rechargeable Lithium Ion Battery 11.1V 2,000mAh Li-Polymer	Same
Suction levels (Massage)	50-180 mmHg	50-130 mmHg	Different
Suction levels (Expression)	50-270 mmHg	50-270 mmHg	Same
Cycles per minute (Massage)	70 to 105 cpm	38 to 70 cpm	Different
Cycles per minute (Expression)	38 to 58 cpm	38 to 70 cpm	Different
Suction levels	15 Levels for expression, 5 levels for massage	12 Levels for expression, 5 levels for massage	Different
Adjustable Suction Levels	Yes	Yes	Same
Mobile Application	No	No	Same
Design	Tabletop pump with separated pump and Flange	Tabletop pump with separated pump and Flange	Same

The indications for use of the subject and predicate devices are identical, and both devices have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including tabletop design, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate devices, including different overall vacuum/cycle specifications and available modes. The different technological characteristics of the subject devices, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

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)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

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

Electrical Safety

Testing was conducted in accordance with ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), IEC 62133-2:2017, 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, and 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 environment.

Electromagnetic Compatibility

Testing was conducted in accordance with IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: "*General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests."*

Software

Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device 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.
- Use life 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.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

10. Conclusion

The results of the performance testing described above demonstrate that Spectra S1 Pro and Spectra S2 Pro are as safe and effective as the predicate device and support a determination of substantial equivalence.