June 30, 2023

Lansinoh Laboratories, Inc.
Lindsay Ewers
Director of Quality Assurance
99 Canal Center Plaza, Suite 550
Alexandria, VA 22314

Re: K230469
Trade/Device Name: Compact Wearable Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 31, 2023
Received: May 31, 2023

Dear Lindsay Ewers:

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)*
K230469

Device Name
Compact Wearable Pump

Indications for Use *(Describe)*
The Compact Wearable Pump is intended to express and collect breastmilk from lactating women for the purpose of feeding collected breastmilk to a baby. The Compact Wearable Pump 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K230469

1. Submitter Information

Applicant: Lansinoh Laboratories Inc.
Contact: Lindsay Ewers
Phone: (727) 542-3743
Email: lewers@lansinoh.com
Address: 99 Canal Center Plaza, Suite 550
Alexandria, VA 22314
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2. Correspondent Information

Contact: Lindsay Ewers
Director of Quality Assurance
Firm: Lansinoh Laboratories

3. Date prepared: June 29, 2023

4. Device Information

Device Name:	Compact Wearable Pump
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:	Lansinoh Smartpump 3.0 Double Electric Breast Pump
510(k) Number:	K222726
Manufacturer:	Lansinoh Laboratories

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

6. Device Description

The Compact Wearable Pump is a battery-powered breast pump which consists of the following components: pump body, breast flange, flange insert, diaphragm, manifold disk, collection cup, charging cord, and carrying bag. The subject device is capable of single pumping or double pumping (using both packaged pumps independently). It is provided non-sterile and can be re-used by a single user. It does not incorporate off-the-shelf (OTS) software or wireless technology/mobile app software functionality. The subject device cannot be operated while plugged into AC power.

The Compact Wearable Pump is designed to work in a user's bra. The main body includes a press-button user interface, pump body, and LED indicator lights. The user interface allows the user to switch from stimulation to expression mode and control the vacuum levels within those modes. Stimulation mode consists of 8 vacuum levels and fixed cycle speeds when used. Expression mode includes 8 vacuum levels with three different cycle speed configurations that vary duration between suction and let down for further customization by the user.

The Compact Wearable Pump is capable of providing vacuum levels from 36-159 mmHg with cycling rates of 1.67-3.04 cycles per second in stimulation mode and vacuum levels from 78-280 mmHg with cycling rates from 0.53-1.99 cycles per second dependent on which expression mode is used. The Compact Wearable Pump is charged with a 5 V DC USB type C adaptor and powered by a 3.8 V, 1300mAh internal rechargeable lithium-ion battery.

The breast pump expresses breast milk by creating a seal around the nipple using a flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

All other components (i.e., motor unit) of the subject device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Compact Wearable Pump is intended to express and collect breastmilk from lactating women for the purpose of feeding collected breastmilk to a baby. The Compact Wearable Pump is intended for a single user.

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

	Compact Wearable Pump K230469 Subject Device	**Smartpump 3.0 Double Electric Breast Pump K222726 Predicate Device**	**Comparison**
Product Code	HGX	HGX	**Same**
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	**Same**
Regulatory Class	Class II	Class II	**Same**
Patient Population	Lactating Women	Lactating Women	**Same**
Indications for Use	The Compact Wearable Pump is intended to express and collect breastmilk from lactating women for the purpose of feeding collected breastmilk to a baby. The Compact Wearable Pump is intended for a single user.	The Lansinoh Smartpump 3.0 Double Electric Breast Pump is intended to express and collect the breastmilk of a nursing woman for the purpose of feeding collected breastmilk to a baby. The pump is intended for a single user.	**Same Intended Use**
Pump Options	Single or Double	Single or Double	**Same**
Cycling control mechanism	Microcontroller	Microcontroller	**Same**
Backflow Protection	Yes	Yes	**Same**
Mobile Application	No	No	**Same**
Indicators	Yes, LED indicators	Yes, LCD display and LED indicators	**Similar**
Single User	Yes	Yes	**Same**

Media separation (backflow protection)	Yes	Yes	**Same**
Expression pattern	2-Phase	2-Phase	**Same**
Expression modes	3 styles	3 styles	**Same**
Suction levels (Stimulation)	36-159 mmHg	78-170 mmHg	**Different. Differences in massage suction levels do not raise different questions of safety and effectiveness**
Suction levels (Expression)	78-280 mmHg	119-280 mmHg	**Different. Differences in pumping suction levels do not raise different questions of safety and effectiveness**
Cycles per Second (stimulation)	1.67-3.04	1.61-2.56	**Different. Differences in available cycle speed do not raise different questions of safety and effectiveness.**
Cycles per Second (Expression)	Mode 1: 0.74-1.99 Mode 2: 0.64-1.72 Mode 3: 0.53-1.32	0.61-1.74	**Different. Differences in available cycle speed do not raise different questions of safety and effectiveness.**
Suction levels	8 vacuum levels	8 vacuum levels	**Same**
User Interface	On-Off switch, vacuum adjustment, Pump style switch	On-Off switch, vacuum adjustment, double/single pumping, Pump style switch	**Different. Differences in available suction levels do not raise different questions of safety and effectiveness.**
Adjustable Suction Levels	Yes	Yes	**Same**
Design	Wearable Milk Collector and Flange	Tabletop Milk Collector and Flange	**Different. Differences in overall design do not, on their own, raise different questions of safety and effectiveness.**
Power Supply	3.8 V, 1300 mAh Lithium-Ion Polymer battery	AC adapter or 7.4 V, 1500 mAh Lithium-Ion Polymer battery	**Different. Differences in available power supply do not raise different questions of safety and effectiveness as performance is independently assessed for each available power configuration.**

The indications for use of the subject and predicate device are similar, and they 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 expression mode options, control mechanism, backflow protection, and device indicators. However, as shown in the table above, there are technological differences between the subject and predicate device, including different vacuum and cycle specifications, power supply, wear configurations, and vacuum levels. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies on the patient-contacting components of the subject device, including irritation, cytotoxicity, and sensitization testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process",* as follows:

- 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

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 for a moderate level of concern as recommended in the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

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 the Compact Wearable Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.