December 23, 2022

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

Re: K222726
Trade/Device Name: Smartpump 3.0 Double Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 2, 2022
Received: December 2, 2022

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 and Part 809); 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,

Reginald K. Avery -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)*
K222726

Device Name
Smartpump 3.0 Double Electric Breast Pump

Indications for Use *(Describe)*
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.

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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1. SUBMITTER

Applicant: Lansinoh Laboratories, Inc.
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Date Prepared: December 22, 2022

2. DEVICE

Device Trade Name:	Smartpump 3.0 Double Electric Breast Pump
Device Common Name:	Powered breast pump
Regulation Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulatory Class:	Class II
Product Code:	HGX

3. PREDICATE DEVICE

Predicate Device: Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2) [K182749]

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

4. DEVICE DESCRIPTION

The Lansinoh Smartpump 3.0 Double Electric Breast Pump is a double electric breast pump intended to express the breast milk of a nursing woman. The pumping can be performed on one breast or on both breasts at the same time. The pumps can be powered by a rechargeable 7.4 V, 1,500 mAh lithium-ion battery or by an AC adapter that is provided with each pump. The pumping system consists of a diaphragm-type vacuum pump which is driven by a microprocessor-controlled DC electric motor. The user interface consists of a front panel keypad

and LCD display. The user is able to adjust cycle mode and vacuum level based on personal comfort and preference.

5. INTENDED USE/INDICATIONS FOR USE

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.

6. SUBSTANTIAL EQUIVALENCE

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2) [K182749]).

Table 1: Technological Comparison

	Subject Device Lansinoh® Smartpump 3.0 Double Electric Breast Pump	**Predicate Device** Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2)
510(k) Number	K222726	K182749
Indications For Use	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.	The Lansinoh® Smartpump™ 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 multiple users, and single users.
Applicant	Lansinoh Laboratories	Lansinoh Laboratories
Classification Regulation	884.5160	884.5160
Product Code	HGX	HGX
Regulatory Class	Class II	Class II
Patient Population	Lactating Women	Lactating Women
Suction Modes	Stimulation and Expression	Stimulation and Expression
Suction Levels (stimulation)	59-236 mmHg	46-140 mmHg
Cycles per Second (stimulation)	1.36-2.69	1.61-2.33
Suction Levels (expression)	89 mmHg – 280 mmHg	95 mmHg – 280 mmHg
Cycles per Second (expression)	0.53-1.83	0.58 – 1.69

	Subject Device Lansinoh® Smartpump 3.0 Double Electric Breast Pump	**Predicate Device** Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2)
Suction Settings	8	8
Expression modes	3	3
Power Supply	AC Adapter Replaceable, rechargeable 7.4 V, 1,500 mAh lithium-ion polymer battery	AC Adapter 6 AA alkaline batteries
Pumping Option	Single or Double	Single or Double
Back Flow Protection	Yes	Yes
Let Down Function	Yes	Yes
Cycling/Suction Control Mechanism	Microprocessor with internal program memory	Microprocessor with internal program memory
Program Memory	32K flash ROM, 2K RAM memory	32K flash ROM, 2K RAM memory
Communication with mobile app	Bluetooth BLE 4.2	Bluetooth version 4.1
Expected Use Life	500 hours	500 hours
Accessories	Tubing with Velcro Strap; Flange Cap; Diaphragm; Breast Flange Body; Comfort Fit Breast Flange (Cone); Cone Soft Edge; White Valve; 5 oz Container; Container Ring; Sealing Disk; Storage Lid	Tubing with Velcro Strap; Flange Cap; Diaphragm; Breast Flange Body; Comfort Fit Breast Flange (Cone); Cone Soft Edge; White Valve; 5 oz Container; Container Ring; Sealing Disk; Storage Lid
Wireless Connectivity	Bluetooth BLE 4.2 with an optional mobile app	Bluetooth with an optional mobile app

The subject device has the same intended use, but different technological characteristics compared to the predicate. The subject and predicate device operate at different cycle speeds, levels, and suction strengths for stimulation and expression modes, and power supply. The predicate device is also indicated for multiple and single users while the subject device is indicated for single users only. The differences in the indications and technological characteristics do not raise different questions of safety and effectiveness.

7. PERFORMANCE DATA

Biocompatibility Testing

The patient contacting components, in their final finished form, are identical to the Smartpump 1.0 Double Electric Breast Pump cleared in K182749 in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Therefore, no additional biocompatibility testing was conducted.

The milk contacting components are those components that are provided in the pump kit. All materials in contact with milk have been tested to meet FDA's Food Additive criteria (21 CFR 175-179)

Electrical safety and electromagnetic compatibility (EMC)

The Smartpump 3.0 Double Electric Breast Pump was tested in accordance with IEC 60601-1:2005 (3rd ed) + CORR. 1:2006 + CORR.2:2007+A1:2012 *Medical electrical equipment: Part 1: General requirements for basic safety and essential performance* including US deviations, with the exception of Clause 11.7 regarding biocompatibility. The device passed all tests.

The Smartpump 3.0 Double Electric Breast Pump was tested in accordance with the FDA-recognized standard IEC 60601-1-2:2014+A1:2021, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests*. The device passed all tests.

The Smartpump 3.0 Double Electric Breast Pump was tested in accordance with 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*. The device passed all tests

The Smartpump 3.0 Double Electric Breast Pump was tested in accordance with the FDA-recognized standard, 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 found to comply with all relevant sections.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." and in accordance with IEC 62304:2016, *Medical device software - Software life cycle processes*. The software for this device was considered as a Moderate level of concern.

Cybersecurity documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*"

Sterilization, Cleaning, and Shelf-Life

Sterilization and Cleaning

The device is reusable, provided non-sterile, and is not sterile when used. Cleaning instructions are provided in the labeling.

Shelf-Life

Shelf-life is not applicable due to the low likelihood of time-dependent product degradation. However, in accordance with IEC 60601-1:2005/(R)2012 the subject devices expected use-life is 500 hours. In testing, the devices were demonstrated to operate within specifications for up to 500 hours of continuous operation at the maximum setting (Expression mode 3, Level 8).

Bench Testing

The following bench testing was performed to demonstrate substantial equivalence:

- Battery life Testing

  Battery life was measured with the pumps at the highest level ((Expression Mode 3, Level 8). The "fail time" was defined as the number of minutes the pump could run at this level before dropping below specifications. Testing supports that the battery life of the device, as noted in the labeling, is approximately 2 hours.

- Suction Pressure Stability Testing

  Devices were evaluated for suction performance at each of the available settings. The suction curves for each cycle mode and suction level demonstrated that the device meets its specifications and performs within the specified working ranges of pressure and cycle speed for each mode/level.

- Backflow Testing

  The Lansinoh pumps are designed as a closed milk collection system. The diaphragm provides a physical barrier, preventing breastmilk from flowing into the tubing or pump body. There have been no changes to the Backflow Protection mechanism materials used in the subject device since its previous clearance in K182749. Therefore, Backflow Protection data from K182749 can be leveraged to support the biocompatibility of the subject devices. The purpose of the backflow test is to demonstrate that the design prevents backflow into the tubing and pump. Devices were tested at maximum pressure/cycle settings (Expression Mode 3, Level 8) at various orientations to simulate worst-case conditions. The testing demonstrated that no milk was present in test devices' tubing during and following the test; therefore, the diaphragm was demonstrated to prevent back flow of milk into the tubing and pump.

8. CONCLUSION

The results of the testing described above demonstrate that the Smartpump 3.0 Double Electric Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.