June 12, 2019

Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.
℅ Lindsay Ewers
Director of Quality Assurance
Lansinoh Laboratories
333 N. Fairfax Street, Suite 400
Alexandria, VA 22314

Re: K182749
Trade/Device Name: Lansinoh® Signature Pro™ Double Electric Breast Pump (DEBP 2.1)
Lansinoh® Smartpump™ Double Electric Breast Pump (DEPB 2.2)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 16, 2019
Received: May 17, 2019

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,

Sharon M. Andrews
Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182749

Device Name
Lansinoh® Signature Pro™ Double Electric Breast Pump (DEBP 2.1)
Lansinoh® Smartpump™ Double Electric Breast Pump (DEPB 2.2)

Indications for Use *(Describe)*
The Lansinoh® Signature Pro™ 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.

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.

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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510(K) SUMMARY

Device Common Name:	Powered Breast Pump
Device Trade Name:	Lansinoh® Signature Pro™ Double Electric Breast Pump (DEBP 2.1) and Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2)
Submitter:	Lansinoh Laboratories Saglık Gerecleri San. Tic. Ltd. Sti. 10006 sokak, No:64 A.O.S.B. Cigli - Izmir 35620 TURKEY Tel: 0090 232 328 05 06 Fax: 0090 232 328 05 58 www.lansinoh.com.tr
Company Contact:	Barbaros Karadağ General Manager Lansinoh Laboratories Saglık Gerecleri San. Tic. Ltd. Sti. Tel: +90 232 328 05 06 barbaroskaradag@lansinoh.com.tr
Date Prepared:	June 11, 2019
Classification Regulation:	21 CFR 884.5160, Class II, Powered Breast Pump
Panel:	Obstetrics/Gynecology
Product Code:	HGX – Powered Breast Pump

Indication for Use:

The Lansinoh® Signature Pro™ 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.

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.

Device Description:

The Lansinoh Powered Breast Pumps are 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 pump can be powered by 6 AA batteries or by an AC adaptor that is provided with the 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.

The purpose of this 510(k) is to update the indications for use statement to include use by multiple users. The labeling has been revised to clarify that the collection kits are for single users only and are not to be shared with other users.

Device Comparison Table:

	New Device	**Predicate Device**	**Substantial Equivalence Comparison**
Manufacturer	Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.	Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.	N/A
Device Name	Lansinoh® Signature Pro™ Double Electric Breast Pump (DEBP 2.1) and Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2)	Powered Breast Pump	N/A
510(k) #	K182749	K122474	N/A
Intended Use	The Lansinoh® Signature Pro™ 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. 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	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	Different; the indications for use of the subject devices are different from the predicate in that the subject device is intended for multiple users. However, this difference does not alter the intended use of the device as compared to the predicate.

	New Device	Predicate Device	Substantial Equivalence Comparison
	users, and single users.		
Suction Levels (stimulation)	46-140 mmHg	55 – 140 mmHg	Similar; the subject devices have a slightly lower suction level. However, this difference does not raise different questions of safety and effectiveness.
Cycles per Second (stimulation)	1.61-2.33	1.55 – 2.4	Similar; the subject devices have a slightly different cycle rates. However, this difference does not raise different questions of safety and effectiveness.
Suction Levels (expression)	95 – 280 mmHg	80 – 220 mmHg	Different; the subject device has higher pressure levels for expression than the predicate. However, this difference does not raise different questions of safety and effectiveness.
Cycles per Second (expression)	0.58 – 1.69	0.61 – 1.52	Similar; the subject devices have a slightly different cycle rate. However, this difference does not raise different questions of safety and effectiveness.
Suction Settings	8	8	Same
Expression modes	3	3	Same
Power Supply	a) 6 AA alkaline batteries b) AC Adapter	a) 6 AA alkaline batteries b) AC Adapter	Same
Pumping Option	Single or Double	Single or Double	Same
Back Flow Protection	Yes	Yes	Same
Let Down Function	Yes	Yes	Same

	New Device	Predicate Device	Substantial Equivalence Comparison
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Communication with mobile app (Smartpump only)	Bluetooth	N/A	Different; the subject device (SmartPump) has Bluetooth capability. The addition of Bluetooth communication does not alter the intended use or raise different questions of safety and effectiveness.

Performance Data:

Bench Performance

Suction Curves

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.

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 90 minutes.

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).

Backflow Test

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. 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.

Biocompatibility

There have been no changes to the patient contacting materials used in the subject device since its previous clearance in K122474. Therefore, biocompatibility data from K122474 can be leveraged to support the biocompatibility of the subject devices.

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 EMC

The device was tested for electrical safety in accordance with (ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012) and EMC in accordance with (IEC 60601-1-2:2007). The device was demonstrated to meet applicable test limits for electrical safety and EMC per the cited standards.

Software and Cybersecurity

The software was evaluated as a minor level of concern per FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005. Documentation consistent with a minor level of concern demonstrated the software functions as intended.

Cybersecurity for the subject devices was evaluated through a risk-based approach. Appropriate mitigations were implemented based upon the level of risk of the devices.

Substantial Equivalence Conclusion:

The purpose of this 510(k) is to establish substantial equivalence of the Lansinoh® Signature Pro™ Double Electric Breast Pump (DEBP 2.1) and Lansinoh® Smartpump™ Double Electric Breast Pump (DEBP 2.2) to the previously cleared Lansinoh Double Electric Breast Pump (K122474).

The subject device indications are different from that of the predicate in that they allow for multiple users. This difference does not alter the intended use of the subject device from that of the predicate.

The subject devices have slightly different technological characteristics as described in the table above. However, the technological differences do not alter the intended use of the subject device as compared to the predicate or raise different questions of safety and effectiveness. The technological differences were evaluated through performance testing that demonstrated that the subject device is as safe and effective as the predicate.

Therefore, the subject devices are substantially equivalent to the predicate.