February 9, 2022

Willow Innovations, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
Warren, NJ 07059

Re: K213311
Trade/Device Name: Lucy Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 7, 2022
Received: January 11, 2022

Dear Dave Yungvirt:

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, 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)*
K213311

Device Name
Lucy Breast Pump

Indications for Use *(Describe)*
The Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast 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

K213311

I. SUBMISSION INFORMATION

Submitter's Name:	Willow Innovations, Inc.
Submitter's Address:	1975 W. El Camino Real, Suite 306 Mountain View, CA 94040
Submitter's Telephone:	Phone: 925-989-8681 Fax: 650-938-5814
Contact Person:	Nelson Lam Vice President of Clinical, Regulatory, Quality nlam@willowpump.com
Date Summary Prepared:	February 2, 2022

II. DEVICE INFORMATION

Trade/Device Name:	Lucy Breast Pump
Common Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Regulatory Class:	II
Product Code:	HGX (Pump, Breast, Powered)

III. PREDICATE DEVICE INFORMATION

Predicate Name:	Pump In Style®
Predicate Manufacturer:	Medela LLC
510(k) Number:	K200508

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

IV. DEVICE DESCRIPTION

The Lucy Breast Pump (Lucy) is a cordless, software-controlled, battery powered breast pump that is intended for use by lactating women to express and collect breast milk. The Lucy Breast Pump is intended for a single user and provided as a non-sterile device. The user has the option to pump from one breast (single pumping) or two breasts simultaneously (double pumping). The fully assembled Lucy Breast Pump, consisting of the Flange, Pump Body, Pump Diaphragm, and Container Assembly, is designed to work in the user's nursing bra that allows it to be used hands-free.

The Lucy Breast Pump provides two operational modes (stimulation and expression), with three vacuum/cycle levels in stimulation mode and four vacuum/cycle levels in expression mode.

Switching between modes and changing the levels within each mode is done through the physical interface on the pump.

V. INDICATIONS FOR USE

The Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast Pump is intended for a single user.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

The following table compares the subject device to the predicate with respect to the intended use and technological characteristics:

Attribute	Subject Device K213311 Willow Innovations, Inc.	Predicate Device K200508 Medela LLC	Comparison
Indications for Use	The Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast Pump is intended for a single user.	Pump In Style® is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This powered breast pump is intended for a single user and is intended to be used in a home environment.	The subject and predicate device indications for use are not identical; however, they have the same intended use (i.e., to collect milk from the breasts of lactating women).
Single-User Device	Yes	Yes	Same
Pumping Options	Single or Double	Single or Double	Same
Design	Combined pump and collection system to be placed within nursing bra	Pump kit in contact with breast, with vacuum tubing going to the pump	**Different:** The assembled subject device is placed within a nursing bra, while the pump component of the predicate device is not part of the physical pump kit, but rather is separate from the pump kit and connected via vacuum tubing. This difference does not raise different questions of safety and effectiveness (S&E)
User Control	On / Off button Mode button (Stimulation/Expression) Suction Increase button Suction Decrease button	On / Off button Let-Down button Suction Increase button Suction Decrease button	Similar
Visual Indicator	LED Light	No visual indicator	**Different:** The subject device includes an LED that provides information to the user of battery charge state as well as the status of device operation. This

			difference does not raise different questions of S&E.
Breast Shields/Flange	Circular Shape – Polypropylene flange	Oval Shape - Polypropylene and thermoplastic elastomer polypropylene breast shields	**Different**: These components have different shapes and materials. The differences do not raise different questions of S&E, as they have the same function to fit over the nipple, create a seal during a pumping session, and to transfer expressed milk to the collection bottle.
Replaceable/ detachable components of the breast pump	Flange Pump diaphragm Container Back Container Bowl Container Duckbill Valve Charging Cable	Breast Shield Membrane Connector Body Connector Cap Tubing Power Supply	**Different**: The subject and predicate devices have differences in replaceable device components. These differences do not raise different questions of S&E.
Power Source	Internal Non-Replaceable Rechargeable Li-Ion Battery Charged with AC Power Adapter Input: 100-240V Vac, 50/60Hz 0.28A Output: 5V DC 2A max	Direct Plug-in - Switching Power Supply: Input: 100-240 VAC, 50/60Hz, 0.7A. Output: 9VDC, 2A External Battery: Pack AA batteries (Alkaline, Ni-MH) Portable Vehicle Adapter: Switching vehicle power adapter Input Rating: 12-24VDC Output Rating: 9VDC, 1.0A	**Different**: The subject device operates only under battery power, while the predicate device can be operated using three power sources. Differences in power sources do not raise different questions of S&E.
Control Mechanism	Microcontroller	Microcontroller	Same
Software	Embedded	Embedded	Same
Electrical Insulation Class	Class II (double insulated)	Class II (double insulated)	Same
IP-Protection	IP-22	IP-22	Same
Protection Type	BF	BF	Same
Vacuum Type	Diaphragm-type assembly	Accumulator	**Different:** Differences in vacuum type do not raise different questions of S&E.
Maximum Vacuum	-295 mmHg	-295 mmHg	Same
Vacuum Range (single and double pumping)	-75 to -280 mmHg	-50 to -240 mmHg	**Different**: The vacuum range is higher for the subject device than the predicate device. This difference does not raise different

			questions of S&E, as the maximum vacuum for both devices is the same.
Cycle Speed Range	30 - 100 cycles/minute	20-140 cycles/minute	**Different:** The subject and predicate devices have differences in their cycle speed ranges. Differences in cycle speed ranges do not raise different questions of S&E.
Backflow/Overflow Protection	Yes - Diaphragm prevents overflow of milk into the pumping mechanism.	Yes - connector with silicone membrane prevents milk overflow into the tubing and pumping mechanism.	Similar

The subject and predicate device have the same intended use, i.e., to express and collect milk from the breasts of lactating women.

The subject and predicate device have different technological features as noted in the table above. These technological differences do not raise different questions of safety or effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Non-clinical testing was conducted to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device, as follows:

Electrical Safety/Electromagnetic Compatibility:

Testing was conducted in accordance with:

- ANSI/AAMI ES60601-1:2005/(R)2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 - Medical electrical equipment - Part 1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ANSI/AAMI/IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: Electromagnetic disturbances - Requirements and tests
- 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
- UN 38.3 – (Article 38.3 of Part 3 of the UN Manual of transport tests and standards for dangerous goods) - Certification for Lithium Batteries
- UL 1642 – UL Standard for Safety Lithium Batteries
- UL 2054 2nd edition – Household and Commercial Batteries

Biocompatibility:

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." Testing included:

- Cytotoxicity per ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization per ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Irritation per ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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

Performance Bench Testing:

Bench testing was conducted to demonstrate pump performance met established specifications in the following areas:

- Vacuum pressure and cycle rate testing was conducted at all settings and demonstrated that the device met its specifications.
- Backflow testing was conducted to demonstrate that liquid does not backflow into the pump.
- 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 reflects the minimum number of pumping sessions remaining at each color level as stated in device labeling.
- Battery charging testing to demonstrate the duration of time needed to fully recharge the battery.

Software:

- Software verification and validation was conducted in accordance with the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" to support a moderate level of concern.

Reprocessing

- A cleaning validation study was conducted and supporting information provided in accordance with the 2015 FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

VIII. CONCLUSION

The subject and predicate device have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is as safe and effective as the predicate device and supports the determination of substantial equivalence.