



October 16, 2023

Willow Innovations, Inc.
Shruti Jayakumar
Director of Global Regulatory Affairs
1975 W. El Camino Real, Suite 306
Mountain View, CA 94040

Re: K230570
Trade/Device Name: Willow[®] Generation 3 Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 13, 2023
Received: September 13, 2023

Dear Shruti Jayakumar:

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: 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.

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.

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,


Jason Roberts -S

Jason R. Roberts, 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

Indications for Use

510(k) Number (if known)
K230570

Device Name
Willow® Generation 3 Breast Pump

Indications for Use (Describe)

The Willow® Generation 3 Breast Pump is intended to express milk from lactating women in order to collect breast milk from their breasts. The device 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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510(K) SUMMARY

Sponsor/Submitter:	Willow Innovations, Inc. 1975 W. El Camino Real, Suite 306 Mountain View, CA 94040
Contact Person:	Shruti Jayakumar Director of Global Regulatory Affairs Phone: 408-335-3106 Email: shruti.jayakumar@onewillow.com
Date Prepared:	September 12, 2023
Device Trade Name:	Willow [®] Generation 3 Breast Pump
Common Name:	Powered Breast Pump
Regulatory Class:	Class II
Regulation Number:	21 CFR 884.5160
Regulation Name:	Pump, Breast, Powered
Product Code:	HGX (Powered, Breast, Pump)
Predicate Device:	Willow [®] Wearable Breast Pump 2.0 (K191577), Willow Innovations, Inc. (submitted under manufacturer name “Exploramed NC7, Inc.”) The predicate device has not been subject to a design-related recall.
Indications for Use:	The Willow [®] Generation 3 Breast Pump is intended to express milk from lactating women in order to collect breast milk from their breasts. The device is intended for a single user.

Device Description

The Willow Gen 3 is a small electromechanical breast pump intended for lactating women to express and collect breast milk. It is a reusable single user device which is provided non-sterile. The device consists of a Pump, Flange, Flextube, and either Milk Bag (single use, disposable) or Milk Container (multiple use, reusable) assembled into one unit and is designed to fit on the user’s breast. The pump component does not come into direct or indirect contact with the breast milk. Users can pump one breast using one Willow Pump or pump both breasts simultaneously using two Willow pumps. The device operates on a battery which can be charged with the provided charger using a standard 120V wall outlet.

Two pumping modes are provided: stimulation and expression. The pump is controlled by the user through either the tactile buttons on the pump or optionally through the Mobile App or Apple Watch App.

Predicate Device Comparison

Attribute	Predicate Device: Willow Gen 2 (K191577)	Subject Device: Willow Gen 3
Manufacturer	Willow Innovations, Inc. (previous company name was Exploramed NC7, Inc.)	Same
Trade Name	Willow Wearable Breast Pump 2.0	Willow Generation 3 Breast Pump
Common Name	Powered Breast Pump	Same
Regulation	Class II, 21 CFR Part 884.5160	Same
Product Code	HGX	Same
Indications for Use	The Willow Breast Pump is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	The Willow Breast Pump is intended to express milk from lactating women in order to collect breast milk from their breasts. The device is intended for a single user. Same. The word “breast” has only been added for clarification.
Intended Use	Express breast milk from breast	Same
Target Population	Lactating women	Same
Single User	Yes	Same
Non-Sterile	Yes	Same
Reusable	Yes	Same
Direct User Contact	Yes	Same
Breast Interface Material	Polypropylene	Same
Technological Characteristics	Electrical pressure control pumping system to generate suction	Same
Closed System?	Yes	Same
Power Source	AC Adaptor or Li-Ion Battery	Same

Attribute	Predicate Device: Willow Gen 2 (K191577)	Subject Device: Willow Gen 3
Suction Levels	60-245 mmHg	40-245 mmHg Same upper limit
Maximum Suction Level (mmHg)	270 mmHg	Same
Adjustable Suction Levels and number of settings	Yes, 7 levels.	Same
Suction Cycles (cycles/second)	1-1.5	0.7 to 1.5 Same upper limit
Backflow Protection	Yes	Same
Control Mechanism	Microcontroller	Same
Single or Double Pumping	Both	Same
# of Phases	Two (2): Stimulation Expression	Same
Milk Collection Apparatus	<ul style="list-style-type: none"> • Milk Bag and Flange • Milk Container and Container Flange 	Same
Milk collection volume (ounces)	4 oz	Same
Flange / Container Flange Sizes	Flange: 21mm, 24mm and 27mm	Same
Number of Reusable Components (in addition to pump)	<ul style="list-style-type: none"> • 2 for disposable Milk Bag (Flextube and Flange) • 3 for reusable Milk Container (Flextube, Container Flange, and Milk Container) 	Same
Mobile App (optional)	View pumping history	Expanded features to allow user to control the pump

The technological characteristics of the Gen 3 and the previously cleared breast pump are similar to the predicate. The indications for use of the subject and predicate devices are the same. The minor modifications to the suction levels, cycles, and app features do not raise new questions of safety or effectiveness. These changes were made to improve the user experience and ensure continued reliability

of the device. The mechanism of action and the principles of operation remain the same as the previously cleared Willow Gen 2 (K191577).

Summary of Non-Clinical Performance Testing

Software

Software was evaluated for a minor level of concern as recommended in the 2005 FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The addition of the optional feature to control the pump via mobile app or Apple Watch did not change the level of concern. No new questions of safety and effectiveness were raised with testing.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing were completed per the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-6 Edition 3.1 2013-10 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-11 Edition 2.0 2015-01 - 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
- ANSI AAMI IEC 60601-1-2:2014 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances – Requirements and tests

All testing passed and all requirements were met. No new questions of safety and effectiveness were raised with this testing.

Performance Testing

Performance testing was conducted to demonstrate that the device meets its specifications and performs as intended. These tests included:

- Vacuum level verification at each level/cycle
- Use life testing
- Battery performance testing
- Battery status indicator testing

All testing passed and all requirements were met. No new questions of safety and effectiveness were raised with this testing.

Substantial Equivalence

Per the FDA Guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” issued July 28, 2014, the predicate is legally marketed (cleared in K191577), the devices have the same intended use, and they have the same technological characteristics. The minor technological differences between the Willow Gen 3 and its predicate device do not raise any new questions of safety or effectiveness. The results from the testing meet the previous performance requirements established for Willow Gen 2. The conclusions drawn from the nonclinical tests demonstrate that the Willow Gen 3 is as safe and effective and performs as well as the previously cleared Willow Gen 2. Thus, the Willow Gen 3 and the Willow Gen 2 are substantially equivalent.