



September 6, 2019

Exploramed NC7, Inc.
Steve Holmes
Chief Product Officer
1975 W. El Camino Real, Suite 306
Mountain View, CA 94040

Re: K191577
Trade/Device Name: Willow Wearable Breast Pump 2.0
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 7, 2019
Received: August 8, 2019

Dear Steve Holmes:

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,

For
Sharon M. Andrews
Acting 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)

K191577

Device Name

Willow Wearable Breast Pump 2.0

Indications for Use (Describe)

The Willow Wearable Breast Pump 2.0 is intended to express milk from lactating women in order to collect 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 – K191577

Sponsor/Submitter: Exploramed NC7, Inc
1975 W. El Camino Real, Suite 306
Mountain View, CA 94040

Contact Person: Steve Holmes
Chief Product Officer
Phone: 650 559 5805
Email: sholmes@willowpump.com

Date Prepared: September 5, 2019

Device Trade Name: Willow® Wearable Breast Pump 2.0

Common Name: Breast Pump

Device Classification: Class II

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered Breast Pump

Product Code: HGX (Pump, Breast, Powered)

Predicate Device: Athena Breast Pump (K161266)
The predicate device has not been subject to a design-related recall.

Device Description: The Willow Wearable Breast Pump 2.0 (Willow) is a small electric breast pump that is intended for lactating women to express and collect breast milk. Willow may be operated as a single or double pumping system. For a user to pump both breasts simultaneously, she would need to use two Willow devices at the same time, one on each breast. Willow is for use by a single user only.

Willow is a battery-powered electro-mechanical device that contains software. The device includes the following main components: Pump, milk collection component (milk bag or container), and a charger.

All milk contacting components of the device are compliant with 21 CFR 174-179.

This submission was for clearance of modifications made to the predicate device, including addition of a milk container for milk collection, updates to device firmware, inclusion of Bluetooth for connection to an optional mobile app, and a change in the flange attachment method.

Indications for Use: The Willow Wearable Breast Pump 2.0 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 indications for use for the subject device is identical to the predicate device. Therefore, the intended use of the subject and predicate devices is the same (express and collect milk from breasts of lactating women).

Predicate Device Comparison

Attribute	Subject Device Willow Wearable Breast Pump	Predicate Device Exploramed NC7 Athena Breast Pump
510(k) number	K191577	K161266
Single User	Yes	Yes
Single/double pump	Single or double	Single or double
Media separation (backflow protection)	Yes	Yes
Cycling control mechanism	Microcontroller	Microcontroller
Specifications		
Power supply	Li Ion battery	Li Ion battery
Suction levels (stimulation)	60 – 105 mmHg	60 -125 mm Hg
Suction levels (expression)	60 - 245 mm Hg	60 - 245 mm Hg
Cycles per second (stimulation)	1.5	1.5
Cycles per second (expression)	1	1
Maximum vacuum	270 mmHg	270 mmHg
Suction levels	7	7
User Interface		
User Control	On-off Switch Vacuum adjustment	On-off Switch Vacuum adjustment
Adjustable Suction Levels	Yes	Yes
Mobile Application	BLE connectivity with an optional Mobile App	No
Design	Milk container and insert Milk bag and flange	Milk bag and flange
Flange/Insert size	Insert: 21 mm, 24 mm, and 27 mm	Flange: 21 mm, 24 mm, and 27 mm
Material		
Milk Container	Co-polymer polypropylene and silicone	-
Flange/Insert	Polypropylene (grade changed) and silicone	Polypropylene
Pump Outer Housing	Polycarbonate and Thermoplastic polyurethane	Polycarbonate

The subject device and predicate devices are similar in most of the technological features. However, there are a number of differences between the subject and predicate device that are described below:

- The subject device collects milk into a milk container or milk bag. The predicate device only collects milk into a milk bag.
- The pump firmware was updated. The changes in firmware include the following:
 - Improvement in volume calculation and bag full notification
 - Enhancing initial latch/early pumping experience
 - Stimulation Phase Vacuum level changed from 60-125 mmHg to 60-105 mmHg
- The subject device includes BLE connectivity to connect the pump to an optional Mobile App.

- The features for Flange attachment to pump was changed from mechanical buttons to magnetic closure.
- Material differences.

These differences in technological characteristics do not raise different questions of safety and effectiveness.

Performance Data: The following performance data were provided to assess the device modifications and to support substantial equivalence to the predicate device:

- Bench Testing
 - Vacuum profile testing.
 - Maintenance of device operation and leakage assessment.
 - Pump and milk container flow rate compatibility.
 - Milk container ability to withstand mechanical stresses over anticipated use-life.
- Electrical Safety
 - IEC 60601-1+A1: 2012
 - IEC 60601-1-11:2015
 - IEC 60601-1-6: 2010 + A1:2013
- Electromagnetic Compatibility
 - IEC 60601-1-2:2014 (4th Edition)
- Biocompatibility
 - Sensitization (ISO 10993-10: 2010)
 - Irritation (ISO 10993-10: 2010)
 - Cytotoxicity (ISO 10993-5:2009)
- Software and Cybersecurity
 - Software evaluated as a minor level of concern per FDA guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
 - Cybersecurity evaluated per FDA guidance “Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.”

Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.