January 26, 2024

X6 Innovations
% Lina Kontos
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Re: K231785
Trade/Device Name: Perifit Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 27, 2023
Received: December 27, 2023

Dear Lina Kontos:

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K231785

Device Name
Perifit Pump

Indications for Use *(Describe)*
The Perifit Pump is a wearable electric breast pump 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 – K231785

X6 Innovation's Perifit Pump

I. Submitter:

X6 Innovations
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75008 Paris, France
Phone: +33 6 71 26 46 45
Contact Person: Erica Perrier

Date Prepared: January 22, 2024

II. Device

Name of Device: Perifit Pump
Common or Usual Name: Powered breast pump
Regulation Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Regulatory Class: Class II
Product Code: HGX (Pump, Breast, Powered)

III. Predicate Device:

Elvie Stride (K210936), Chiaro Technology Limited, 2nd Floor 63-66 Hatton Garden, London, GB EC1N 8LE

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

IV. Device Description

The Perifit Pump is an electrically powered wearable single breast pump consisting of the following key components: a housing ("hub") containing pump electronics (motor, valve, PCB, rechargeable battery and associated components), and detachable milk-contacting components: a silicone flange (breast shield), a plastic (polypropylene) connector, silicone diaphragm, a silicone duckbill valve, a plastic bottle. Accessories provided with the Perifit Pump include a screw-on container lid, a USB charging cable, and bra adjustment buckle. The Perifit pump is a closed-system breast pump.

The hub user interface allows the user to power the breast pump on and off, and to operate the breast pump in two modes (stimulation, expression) and to control the vacuum settings within these modes. Each mode consists of 8 vacuum levels, capable of providing suction from 30 to 285 mmHg, with cycle speeds ranging from 68 to 120 cycles per minute in stimulation mode and 28 to 80 cycles per minute in expression mode.

The Perifit Pump is powered by an internal rechargeable lithium-ion polymer battery (3.7V 1500mAh). The breast pump cannot be operated while it is being charged. The Perifit Pump

operates on embedded software, and software updates by end-users are supported. The subject device is intended for use in a home healthcare environment.

An optional smartphone app may be used with the Perifit Pump. The app may be used to control the operation of the breast pump (select mode and vacuum level, start and stop pumping), save pumping session history and display the quantity (in ml) of milk in the bottle on the user's smartphone. Use of the app is not mandatory to operate the Perifit Pump.

The Perifit Pump is a closed-system breast pump with an anti-backflow diaphragm which physically separates the air-pumping system from the milk-flow system.

V. Intended Use / Indications for Use

The Perifit Pump is a wearable electric breast pump intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

VI. Comparison of Intended Use and Technological Characteristics

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1: Substantial Equivalence Table

	Perifit Pump ***Subject Device***	**Elvie Stride (K210936)**	**Comparison**
Product Name	Perifit Pump	Elvie Stride	N/A
Product Code	HGX	HGX	Identical
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Identical
Regulatory Class	Class II	Class II	Identical
Patient Population	Lactating Women	Lactating Women	Identical
Indication for Use	The Perifit Pump is a wearable electric breast pump intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	The Elvie Stride is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Stride is intended for a single user.	Identical
Single/double pump	Single (or Double by using two units simultaneously)	Single or Double	Identical
Cycling control mechanism	Microcontroller	Microcontroller	Identical
Backflow Protection	Yes	Yes	Identical
Suction Modes	Stimulation Mode and Expression Mode	Stimulation mode and Expression mode	Identical
Suction levels	8	10	Similar: the difference in the number of suction levels does not raise different questions of

	Perifit Pump ***Subject Device***	**Elvie Stride (K210936)**	**Comparison**
			safety or effectiveness as the vacuum range is comparable.
Adjustable suction levels	Yes	Yes	Identical
Flange Size	18mm, 21 mm, 24 mm, and 27 mm	15, 17, and 19mm (silicone inserts), 21, 24, 28mm (plastic flanges)	Similar: the difference in flange sizes does not raise different questions of safety or effectiveness as the size range they cover is comparable. The user will select the specific size that works best and is comfortable.
Vacuum range	-30 to -300 mmHg	-55 to -300mmHg in single pumping mode (-35 to -260mmHg in double pumping mode)	Similar: the difference in specification does not raise different questions of safety or effectiveness.
Cycle speed: Stimulation	68 to 120 cycles per minute	31 to 83 cycles per minute	Similar: the difference in specification does not raise different questions of safety or effectiveness.
Cycle speed: Expression	28 to 80 cycles per minute	18 to 51 cycles per minute	Similar: the difference in specification does not raise different questions of safety or effectiveness.
Controls	On/Off button (which also controls Play/Pause pump function); Increase/decrease vacuum buttons; Mode selection button	On/Off button; Play/pause button; Increase/decrease vacuum buttons, Mode selection button	Identical
Power Supply	Li-Ion Battery	Li-ion Battery	Identical
Indicators	Yes, LED	Yes, LED	Identical
Materials	Milk-contacting parts are made of silicone, polypropylene, and Tritan copolyester (bottle only) Pump Outer Housing: PC/ABS plastic	Milk-contacting parts are made of silicone and polypropylene Pump Outer Housing: ABS plastic	Similar: the difference in bottle/container material does not raise different questions of safety or effectiveness.
Software	Pump operates on embedded software. A smartphone app (optional) may also be used to control the pump	Pump operates on embedded software. A smartphone app (optional) may also be used to control the pump.	Identical Similar: the smartphone apps for both devices provide similar functionalities and any differences do not raise different questions of safety or effectiveness.

The subject device and predicate device have the same intended use. Both the subject and predicate devices work according to the same technological principle. Suction is applied, then released, to the user's nipple in order to stimulate milk expression from a lactating woman's breasts. The user can control the vacuum intensity and select between two suction modes offering faster and slower suction cycles. The milk expressed from the breasts is collected in a collection container that is self-contained within the user's bra. Both systems are closed-system breast pumps with an anti back-flow diaphragm physically separating the air-pumping system from the milk-collecting system. The subject device (hub containing the pump electronics plus milk-contacting elements) is fully contained within the user's bra, while the predicate's milk-contacting elements are fully contained within the nursing bra and connected to the pump using external tubing. Despite the difference in configuration, both pumps operate in the same manner, using an anti-backflow diaphragm to physically separate the pumping system from the milk collection system.

Both the subject and predicate device have the option of being used in conjunction with a smartphone app. Use of this app is not mandatory for either device, and both the subject and predicate breast pumps can be operated using only the user control interface on the hub.

The Perifit Pump app also includes some additional features that are not available with the predicate (e.g., estimate of milk volume during pumping session, selecting between several suction patterns).

The technological differences between the Perifit Pump and the predicate device do not raise different questions of safety or effectiveness.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2021)
- Skin Irritation (ISO 10993-23:2021).

Results of this testing support the biocompatibility of the device. The user-contacting materials were found to be non-cytotoxic, non-sensitizing, and non-irritating.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing were conducted in accordance with the following standards:

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601- 1:2005/AMD2:2020 plus US National Differences: National standard AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601- 1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 plus US NATIONAL DIFFERENCES - Differences according to US National standard ANSI/AAMI HA60601-1-11:2015+A1: 2021
- IEC 60601- 1-2:2014 + A1:2020, EN 60601- 1-2:2015 + A1:2021, IEC 60601-1 -11:2015 + A1:2020 Clause 12, EN 60601-1 -11:2015 + A1:2021 Clause 12
- IEC 62133-2:2017/AMD1:2021
- Altitude testing of the device battery per UN 38.3

Software verification and validation testing was conducted in accordance with FDA guidance ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", 2005 and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", 2023) and IEC 62304:2006.

All milk-contacting components were tested for compliance with material-specific requirements as outlined in 21 CFR 177.1520, 21 CFR 177.2420 and 21 CFR 177.2600.

Performance testing to substantiate the design and performance of the Perifit Pump included:

- Vacuum level and cycle speed verification testing to demonstrate that the device met cycle speed and suction specifications at all intensity levels in both modes of operation.
- Backflow protection testing to ensure that liquid was not able to come into contact with the air-pumping system.
- Device use life testing to demonstrate that the device maintained its vacuum level and cycle speed specifications over its proposed use life.
- Battery use life testing to demonstrate that the battery maintained its capacity over the number of charging cycles associated with the device use life.
- Battery charge and discharge time to demonstrate that the operating time and charge time of the breast pump device fall within specifications communicated to the user.
- Battery status indicator testing
- Milk level validation testing
- Ingress protection (IP22)
- Packaging drop and vibration testing according to ISTA-3A

Conclusion

The results of the performance testing described above demonstrate that the Perifit Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.