August 11, 2025

Anker Innovations Limited
℅ Tracy Chen
Manager
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue Xili Town
Shenzhen, Guangdong 518000
CHINA

Re: K250207
Trade/Device Name: eufy Wearable Breast Pump S1 (T8DO2);
eufy Wearable Breast Pump E10 (T8DO3)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: July 11, 2025

Dear Tracy Chen:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250207

Device Name
eufy Wearable Breast Pump S1 (T8D02)
eufy Wearable Breast Pump E10 (T8D03)

Indications for Use *(Describe)*
The eufy Wearable Breast Pump S1 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

The eufy Wearable Breast Pump E10 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It 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.

510(k) Summary- K250207

1. Submitter Information

1.1 Applicant information

Applicant Name	Anker Innovations Limited
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Tel.	+86 166 2079 6266
Contact person	Darren Li
E-mail	darren.li@anker.com
Date Prepared	August 9, 2025

1.2 Contact Information

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Website	http://www.cefda.com

2. Device information

Trade name	eufy Wearable Breast Pump S1 (T8DO2) eufy Wearable Breast Pump E10 (T8DO3)
Common Name	Powered breast pump
Regulation Number	21 CFR 884.5160
Regulation Name	Powered breast pump
Classification Panel	Obstetrics/Gynecology
Product code	HGX (Pump, Breast, Powered)
Regulatory Class	Class II

3. Predicate Device Information

Trade Name	Perifit Pump
510(k) Number	K231785
Product Code	HGX
Manufacturer	X6 Innovations

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

4. Device Description

The eufy Wearable Breast Pump is an electrically powered wearable single breast pump. There are two models, eufy Wearable Breast Pump S1 (T8DO2) and eufy Wearable Breast Pump E10 (T8DO3). S1 consists of a Pump Hub, Diaphragm, Milk Container, Pouring Spout, Heating Pins, Flange, Duckbill Valve and charging pins. E10 consists of Pump Hub, Diaphragm, Milk Container, Pouring Spout, Flange and Duckbill Valve.

The differences between S1 and E10 are as follows:

1) E10 has no heating function (S1 has a heating function);

2) The charging method is different (S1 for magnetic charging, E10 for Type-C charging).

The eufy Wearable Breast Pump is powered by an internal rechargeable lithium-ion polymer battery (3.7V 1460mAh). The eufy Wearable Breast Pump cannot be operated while it is being charged.

The eufy Wearable Breast 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 Breast 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 Breast Pump.

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

The eufy Wearable Breast Pump 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 7 vacuum levels, capable of providing suction from -75 to -292.5mmHg, with cycle speeds ranging from 71 to 110 cycles/minute in stimulation mode and 39 to 60 cycles/minute in expression mode.

5. Indication for Use

The eufy Wearable Breast Pump S1 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

The eufy Wearable Breast Pump E10 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

6. Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Items	Proposed Device	Predicate Device	Comparison
510(k) Number	K250207	K231785	N/A
Device Name	eufy Wearable Breast Pump S1 eufy Wearable Breast Pump E10	Perifit Pump	N/A
Model	T8D02: eufy Wearable Breast	/	N/A

	Pump S1 T8D03: eufy Wearable Breast Pump E10		
Indications for Use	The eufy Wearable Breast Pump S1 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user. The eufy Wearable Breast Pump E10 is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	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.	Similar
Patient Population	Lactating Women	Lactating Women	Identical
Single/double pump	Single (or Double by using two units simultaneously)	Single (or Double by using two units simultaneously)	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	7	8	Similar
Adjustable suction levels	Yes	Yes	Identical
Flange Size	15，17，19，21，24，27mm	18mm, 21 mm, 24 mm, and 27mm	Similar
Vacuum range	-75 to -292.5mmHg	-30 to -300 mmHg	Similar
Cycle speed: Stimulation	71 to 110 cycles/minute	68 to 120 cycles per minute	Similar
Cycle speed: Expression	39 to 60 cycles/minute	28 to 80 cycles per minute	Similar
Controls	Power button, switch between stimulation and expression modes (S1 only), stimulation mode (E10 only), expression mode (E10 only), heating on/off (S1 only), +/- (adjust the suction, heat (S1 only) level, and LR paring (S1 only), LR paring (E10 only)	Power button, +/- (adjust suction intensity), pumping mode and intensity level indicator, switch between stimulation and expression modes	Similar
Power Supply	Li-Ion Battery	Li-ion Battery	Identical
Indicators	Yes, LED	Yes, LED	Identical
Materials	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene	Milk-contacting parts are made of silicone, polypropylene, and Tritan copolyester (bottle only) Pump Outer Housing:	Similar

	Styrene (ABS) plastic	PC/ABS plastic	
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.

In comparison to the predicate device, the subject device, eufy Wearable Breast Pump E10 and eufy Wearable Breast Pump S1, has the same intended use and similar indications for use – the expression and collection of breast milk. As seen in the comparison table, the subject and predicate devices have different technological features, including the user interface, vacuum range, cycle speed range, suction levels, materials, and flange size. These technological differences do not raise different questions of safety and effectiveness.

7. Summary of Non-clinical Performance Testing

1) Electrical Safety, Electromagnetic Compatibility

The subject device has passed safety testing in according to following standards.

- ANSI AAMI ES60601-1: 2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]: 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
- IEC 62133-2 Edition1.0 2017-02: 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

2) Performance testing

Performance testing was conducted on the subject device:

- Vacuum Suction pressure & Cycle speed
- Backflow protection
- Battery capacity
- Operating time/charging time
- Use life testing

Device specifications were met for all tests conducted.

3) Packaging simulation testing

The packaging simulation testing was conducted in accordance with ISTA 3A: 2018.

4) Biocompatibility

Biocompatibility testing was conducted in accordance with the 2023 FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."
The subject device has passed biocompatibility testing in according to following standards.

- ANSI AAMI ISO 10993-5:2009/(R)2014: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11: Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01: Biological evaluation of medical devices - Part 23: Tests for irritation

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

5) Software

The subject device contains an embedded software and a mobile application. Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions."*

6) Cybersecurity

The cybersecurity was evaluated according to the 2025 FDA's Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

8. Conclusions

The results of the performance testing described above demonstrate that the subject device, eufy Wearable Breast Pump S1, eufy Wearable Breast Pump E10 is as safe and effective as the predicate device and supports a determination of substantial equivalence.