May 29, 2026

Anker Innovations Limited
Ezra Zeng
Regulatory Engineer
Unit 56, 8th Floor, Tower 2, Admiralty Centre
18 Harcourt Rd.
HONG KONG

Re: K254300
Trade/Device Name: eufy Wearable Breast Pump (T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: April 30, 2026
Received: April 30, 2026

Dear Ezra Zeng:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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)*
K254300

Device Name
eufy Wearable Breast Pump (T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007,T6008, T6009)

Indications for Use *(Describe)*
The eufy Wearable Breast Pump (model: T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007,T6008, T6009) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K254300

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Anker Innovations Limited

Address: Unit 56, 8th Floor, Tower 2, Admiralty Centre, 18 Harcourt Road, Hong Kong

Telephone: +86 15989468306

Contact Person: Ezra Zeng

Contact Title: Regulatory Engineer

Contact Email: ezra.zeng@anker-in.com

Date Prepared: May 29, 2026

2. Device Information

Trade Name: eufy Wearable Breast Pump (T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009)

Model: T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009

Common Name: Powered breast pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered breast pump

Regulatory Class: Class II

Product Code: HGX (Pump, Breast, Powered)

3. Identification of Predicate Device(s)

Predicate Device Name	Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-)
510(K) Number	K253283

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

4. Description of Device

The eufy Wearable Breast Pump is an electrically powered, software-controlled breast pump to be used in a home environment by lactating women to express and collect milk from their breasts. The pump is provided non-sterile, and it is intended for use by a single user. The subject device can be used as a single pump or double pump by using two units simultaneously. The device consists of a pump hub and milk collection components. The eufy Wearable Breast Pump expresses milk by creating a seal around the nipples using the flange and applying and releasing suction to the breasts. The milk is collected in a milk container. To prevent milk from flowing into the vacuum, a backflow protection mechanism physically separates the milk-contacting pathway from the vacuum system.

The pump is powered by a 3.8VDC rechargeable lithium battery and does not function during charging. The rechargeable battery can be charged from the external adapter (not included with the device) through a magnetic charging cable provided with the device, or for some models, by placing the device in a magnetic charging case provided with the device.

The device user interface has 6 buttons allowing the user to power the device on/off, select between two pumping modes (expression and stimulation), control suction strength within each mode (7 levels of suction strength for stimulation mode and 10 levels of suction strength for expression mode), and turn the heating function and vibration massage mode on or off. The device also includes an LED display that includes icons for the current working mode, level, running time, battery status and pairing status when two units are used simultaneously.

The subject device includes an optional mobile app, called eufy App that can be installed on a compatible Android or iOS phone and is used to control the operation of eufy Wearable Breast Pump functions, including power on/off, selection of operating modes and levels, etc. The device has Bluetooth capability that allows connection of the device to the mobile App to control the device.

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

All models in this submission are functionally similar, with differences in terms of the external color, milk container capacity and inclusion of charging case and carry bag.

5. Indications for Use

The eufy Wearable Breast Pump (model: T600P, T6001, T6002, T6003, T6004, T6005, T6006, T6007,T6008, T6009) is a powered breast pump intended to be used by lactating women to express and collect breast milk from their breasts. The device is intended for a single user.

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

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

Device	**Subject device (K254300)** eufy Wearable Breast Pump (T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009)	**Primary Predicate device (K253283)** Momcozy Wearable Breast Pump (BP334-,BP380-, BP420-, BP431-, BP400-, BP432-, BP434-)	**Comparison**
Classification	Pump, Breast, Powered	Pump, Breast, Powered	Same
Regulation	Class II, 21 CFR 884.5160	Class II, 21 CFR 884.5160	Same
Product code	HGX	HGX	Same
Indications for Use	The eufy Wearable Breast Pump (model: T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009) is a powered breast pump intended to be used by lactating women to express and collect breast milk from their breasts. The device is intended for a single user.	The Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-) is a powered 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	Same
Single/double pump	Single (or Double by using two units simultaneously)	Single or double	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Backflow protection	Yes	Yes	Same
Suction modes	Two modes (Stimulation mode and Expression mode)	Three modes (Stimulation mode , expression mode, and mixed mode)	**Different**
Suction levels	Stimulation Mode: 7 levels; Expression Mode: 10 levels	15 levels in all modes	**Different**
Vacuum range (mm Hg)	Stimulation mode: -60 to -210 Expression mode: -77 to -300	Stimulation mode: -65 to -174 Expression mode: -109 to -305 Mixed mode: -65 to -305 (±30 mmHg, except for -305 which is +30mmHg and -10 mmHg)	**Different**
Cycle speed (Cycles per minute)	Stimulation mode: 60- 96 (±2) Expression mode: 32- 52 (±2)	Stimulation mode: 54-90 (±5) Expression mode:25-60 (±5) Mixed mode: 46-84 (±5)	**Different**
Controls	Power button, mode switch button, heating on/off , massage on/off, +/- (adjust the suction, heat level), LR pairing	On/off/pause switch, mode selection switch, decrease pumping level, increase pumping level and Toggle button	**Different**
Power Supply	3.8V Li-Ion Battery	3.7V Li-ion Battery	Similar
Mobile application	Yes	Yes	Same
Design	Wearable	Wearable	Same
Additional Functions	Heating, vibrational massage	None	**Different**

The subject and predicate devices have similar indications for use statements and the same intended use, i.e., the expression and collection of breast milk from the breasts of lactating women.

As noted in the table above, the technological differences between the subject and the predicate device include differences in operating modes, vacuum pressure/cycle frequency specifications,

available suction levels, user interface, maximum vacuum, and additional features including heating and vibrational massage. These technological differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

7. Discussion of Non-Clinical Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

7.1 Biocompatibility Testing

The biocompatibility evaluation for the patient contacting components of the Wearable Breast Pump was conducted in accordance with the 2023 FDA guidance document, “Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process,” including the following tests:

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

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

7.2 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wearable Breast Pump device. The system complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment – Part1: General requirements for basic safety, and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances- Requirements and tests standard for EMC
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

7.3 Software Verification and Validation and Cybersecurity Testing

Software verification and validation was conducted as recommended in the 2023 FDA guidance document, “Content of Premarket Submissions for Device Software Functions” consistent with a basic documentation level. The cybersecurity documentation for the subject device was provided in accordance with 2026 FDA guidance “Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions”.

7.4 Performance and Use Life Verification

Bench performance testing was conducted to evaluate device performance, including:

- **Vacuum pressure and cycle speed verification for all modes and levels of operation**
- Heating and massage mode functional testing

- **Backflow protection testing**
- **Battery charging time, capacity and service time testing**
- **Use life testing**

Device specifications were met for all tests conducted.

8. Substantial Equivalence Conclusion

The results of the performance testing described above demonstrate that the eufy Wearable Breast Pump (T600P, T6000, T6001, T6002, T6003, T6004, T6005, T6006, T6007, T6008, T6009) is as safe and effective as the predicate device and supports a determination of substantial equivalence.