April 2, 2025

Shenzhen TPH Technology Co., Ltd.
Xiaoyan Yang
Quality Engineer
Room 203, 2nd floor, 29th Building,
Lianchuang Technology Park, No.21 Bulan Road, Xialilang
Shenzhen, Guangdong 518100
CHINA

Re: K250152
Trade/Device Name: eufy Wearable Breast Pump S1 (T8D02);
eufy Wearable Breast Pump E10 (T8D03);
eufy Wearable Breast Pump S1 Pro (T8D04);
eufy Wearable Breast Pump E20 (T6060);
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 18, 2025
Received: January 21, 2025

Dear Xiaoyan Yang:

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, PhD
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

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)*
K250152

Device Name
eufy Wearable Breast Pump S1 (T8D02) ;eufy Wearable Breast Pump E10 (T8D03) ;eufy Wearable Breast Pump S1 Pro (T8D04) ; eufy Wearable Breast Pump E20 (T6060)

Indications for Use *(Describe)*
The eufy Wearable Breast Pump S1 (T8D02); eufy Wearable Breast Pump E10 (T8D03); eufy Wearable Breast Pump S1 Pro (T8D04); eufy Wearable Breast Pump E20 (T6060) are intended to express milk from lactating women in order to collect milk from their breasts. These devices are 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 – K250152

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter Information:	Shenzhen TPH Technology Co., Ltd. Room 203,2nd floor,29th Building, Lianchuang Technology Park, No. 21 Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, China. Tel.: +86-13302476262 Contact Person: Xianzi Chen
2. Date Prepared:	April 1, 2025
3. Device name Information:	**Device Name:** eufy Wearable Breast Pump S1 (T8D02) eufy Wearable Breast Pump E10 (T8D03) eufy Wearable Breast Pump S1 Pro (T8D04) eufy Wearable Breast Pump E20 (T6060) **Common Name:** Powered Breast Pump **Regulation Number:** 21 CFR 884.5160 **Regulation Name:** Powered Breast Pump **Product code:** HGX **Regulatory Class:** II
4. Predicate Device Information:	**Device Name**: Wearable Breast Pump (Model S18) **510(k) Number**: K223886 **Manufacturer**: Shenzhen TPH Technology Co., Ltd. The predicate device has not been subject to a design-related recall.

5. Device Description

The eufy Wearable Breast Pump S1 (T8D02); eufy Wearable Breast Pump E10 (T8D03); eufy Wearable Breast Pump S1 Pro (T8D04); eufy Wearable Breast Pump E20 (T6060) is intended to express milk from lactating women in order to collect milk from their breasts. It is an electrically powered, software-controlled, digital single user pump. The device consists of the following key components: flange, pump motor, silicone diaphragm, USB cable, milk collector, bra adjustment buckle, and valve. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free without any external power cords.

There device has two modes of operation - Expression mode and Stimulation mode, with multiple suction

levels for each mode. Both modes consist of nine vacuum levels. Expression mode consists of pressures ranging from 120-245 mmHg and cycle speeds of 20-66 cycles/min and stimulation mode consists of ranges from 40-120 mmHg and cycle speeds of 69-92 cycles/min. There is an LED status display shown on the pump body, which displays the working mode and battery indicator.

The subject device may be operated as a single or double pumping system. For a user to pump both breasts simultaneously, they would need to use two devices at the same time one on each breast. The pump is provided in non-sterile and can be re-used by a single user. The device is powered by a Li-ion battery and charged using a 5V DC adaptor. The device is designed not to be used during charging.

The breast pump does not incorporate any off-the-shelf (OTS) software, and it incorporates embedded software which controls all the features of the product. All milk contacting components of the device are compliant with 21 CFR 177.

6. Indications for Use

The eufy Wearable Breast Pump S1 (T8D02); eufy Wearable Breast Pump E10 (T8D03); eufy Wearable Breast Pump S1 Pro (T8D04); eufy Wearable Breast Pump E20 (T6060) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

7. Predicate Device Comparison

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

Table 1 Specific Comparison to Predicate

Item	**Subject Device** **eufy Wearable Breast Pump [Models E10 (T8D03); E20 (T6060); S1 Pro (T8D04); S1 (T8D02)]** **K250152**	**Predicate Device** **Wearable Breast Pump (Model S18)** **K223886**	**Comment**
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 S1 (T8D02); eufy Wearable Breast Pump E10 (T8D03); eufy Wearable Breast Pump S1 Pro (T8D04); eufy Wearable Breast Pump E20 (T6060) 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 Wearable Breast Pump (Model S18) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	Same
Patient Population	Lactating women	Lactating women	Same
Single user	Yes	Yes	Same
Single/double pump	Single	Single	Same
Backflow protection)	Yes	Yes	Same
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Specifications			
Power Supply	Li-ion battery	Li-ion battery	Same
Suction Modes	Stimulation and Expression	Stimulation and Expression	
Suction Strength (Stimulation)	40 - 120 mmHg	40 - 120 mmHg	Same
Cycle Speed: Stimulation	69 - 92 cycles/minute	69 - 92 cycles/minute	Same
Suction Strength (Expression)	120 - 245 mmHg	120 - 245 mmHg	Same
Cycle Speed:	20 - 66 cycles/minute	20 - 66 cycles/minute	Same

Expression			
Suction levels	9	9	Same
User interface			
User control	On-off switch, vacuum adjustment	On-off switch, vacuum adjustment	Same
Adjustable suction levels	Yes	Yes	Same
Wireless technology	No	No	Same
Component design and quantity	Milk collector (2 /2 /4 / 3), Flange (2 /2 /4 / 3), Pump motor (2/ 2/ 2/ 2), Silicone diaphragm (2 /3 /4 / 3), USB cable (1/ 1/ 1/ 1), Bra adjustment Buckle(1/ 1/ 1/ 1), Valve (2 /3 /4 / 3).	Milk collector (1), Flange (1), Pump motor (1), Silicone diaphragm (1), USB cable (1), Bra adjustment Buckle (1), Valve (1)	**Different**
Milk collector Capacity	180 ml	180 ml	Same
Flange size	21mm, 24mm and 27mm	21mm, 24mm and 27mm	Same
Material			
Milk collector/Linker	Polypropylene	Polypropylene	Same
Flange/Valve/Diaphragm	Silicone	Silicone	Same
Pump motor/outer housing	ABS	ABS	Same

The indications for use of the subject and predicate devices are identical; therefore, they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).
The subject and predicate devices have similar technological features, including device design, pumping options, control mechanism, user interface, backflow protection, device power source, materials, and device indicators. However, as shown in the table above, the subject and predicate devices differ in the quantities of device components included in each model. These differences of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

8. Performance Testing:

Biocompatibility testing

The materials, final finished form, and intended use of the subject device are identical to those of the predicate device (K223886) including formulation, processing, and cleaning. Therefore, biocompatibility information was leveraged from the predicate device to support the biocompatibility of patient-contacting components of the subject device. The milk contacting components of the device are also compliant with 21 CFR 177.

Electrical safety and electromagnetic compatibility (EMC)

The subject device electrical design and components including the power source (Li-ion battery) and charger are identical to those of the predicate device (K223886). Therefore, electrical safety, battery safety and electromagnetic compatibility testing was leveraged from the predicate device to support electrical safety, battery safety and electromagnetic compatibility for the subject device.

Software Verification and Validation Testing

The subject device includes identical software as the predicate device (K223886). Therefore, software documentation, including verification & validation, was leveraged from the predicate device to support the validity of the subject device software-controlled functions.

Performance and Use Life Verification

The subject device has identical functions and mode of operations as the predicate device (K223886) and therefore following testing were leveraged from the predicate device to demonstrate that the device meets its design requirements and performs as intended:

- Vacuum level and cycle frequency testing for each mode/cycle to demonstrate that the device meets mode/cycle specifications.
- Backflow protection testing to verify liquid does not backflow into the tubing.
- Use life testing to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery capacity, service time and charging time testing to demonstrated that battery functions as specified during stated battery use-life.

9. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the eufy Wearable Breast Pump E10 (T8D03); eufy Wearable Breast Pump E20 (T6060); eufy Wearable Breast Pump S1 Pro (T8D04); eufy Wearable Breast Pump S1 (T8D02) is as safe and effective as the predicate device and supports a determination of substantial equivalence.