March 12, 2026

A Cute Baby Inc
Matthew Kho
Managing Director
865 N 1430 W
Orem, Utah 84057

Re: K252583
Trade/Device Name: Mini Moon electric breast pump (PA221); Moon Wave electric breast pump (PA220)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 11, 2026
Received: February 11, 2026

Dear Matthew Kho:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Reginald K. Avery -S

for
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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252583

Device Name
Mini Moon electric breast pump (PA221);
Moon Wave electric breast pump (PA220)

Indications for Use *(Describe)*
The Moon Wave (PA220) and Mini Moon (PA221) Electric Breast Pump is a personal use, electrically powered device used to express milk from the breasts of lactating women. This device is not intended for hospital use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY – K252583

1. Submitter Information

Applicant:	A Cute Baby, Inc. (dba Rumble Tuff)
Address:	865 N 1430 W, Orem, UT 84057 USA
Phone:	(801) 609-8168
Fax:	(801) 796-2688
Website:	www.rumbletuff.com
Contact Person:	Matthew Kho, Director
Date Prepared:	March 11, 2026

2. Device Information

Trade Names:	Moon Wave Electric Breast Pump – Model PA220 Mini Moon Electric Breast Pump – Model PA221
Model Number:	PA220, PA221
Common Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulatory Class:	Class II
Product Code:	HGX (Pump, Breast, Powered)
Panel:	Obstetrics/Gynecology

3. Predicate Device

Manufacturer:	Acute Ideas Co., Ltd.
Device Name:	Rumble Tuff Electric Breast Pump
510(k) Number:	K113315

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

4. Device Description

PA220 – Moon Wave Electric Breast Pump

The PA220 is a countertop-style, electrically powered breast pump intended for single-user home use. The device incorporates dual-phase pumping (Stimulation and Expression modes), adjustable suction levels, and adjustable cycle speeds. It features a numeric LED display, programmable timer, night light, and an integrated silicone diaphragm backflow protection system.

The PA220 is powered by a 12 V DC adapter or an integrated 7.4 V lithium-ion rechargeable battery pack (2S1P configuration).

Performance Parameters:

- Stimulation Mode: 45–124 mmHg; 65–120 cycles per minute (CPM)
- Expression Mode: 45–251 mmHg; 28–60 cycles per minute

PA221 – Mini Moon Electric Breast Pump

The PA221 is a compact, wearable, electrically powered breast pump with a Slim-Cup hands-free collection system. The device incorporates dual-phase pumping (Stimulation and Expression modes) with adjustable suction levels and preset cycle speeds. It features LED suction level indicators and an integrated silicone diaphragm backflow protection system.

The PA221 is powered by a USB-C 5 V adapter or an integrated 3.7 V lithium-ion rechargeable battery pack (1S1P configuration).

Performance Parameters:

- Stimulation Mode: 45–124 mmHg; 72–111 cycles per minute
- Expression Mode: 45–251 mmHg; 38–60 cycles per minute

Materials

The breast- and milk-contacting components of the device (e.g., flange, breast shield body, funnel base, collection bottle, cup, and diaphragm) are manufactured from polypropylene and silicone materials. These materials have been evaluated for biocompatibility in accordance with ISO 10993-1:2018 and FDA guidance and comply with applicable U.S. FDA food-contact regulations under 21 CFR Part 177. Patient-contacting components are made of polypropylene.

5. Indications for Use

The Moon Wave (PA220) and Mini Moon (PA221) Electric Breast Pump is a personal use, electrically powered device used to express milk from the breasts of lactating women. This device is not intended for hospital use.

6. Comparison of Technological Characteristics with the Predicate Device

Characteristic	Predicate Device K113315	Subject Device – Moon Wave (PA220) K252583	Subject Device – Mini Moon (PA221) K252583
Trade Name	Rumble Tuff PA201D	Moon Wave Electric Breast Pump	Mini Moon Electric Breast Pump
Manufacturer	A Cute Baby, Inc.	Acute Ideas Co., Ltd.	Acute Ideas Co., Ltd.
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	21 CFR 884.5160
Regulation Name	Powered Breast Pump	Powered Breast Pump	Powered Breast Pump
Product Code	HGX	HGX	HGX

Device Class	II	II	II
Indications for Use	The Rumble Tuff Electric Breast Pump is an electrically powered single-user device used to express and collect milk from the breasts of lactating women. The device is not intended for hospital use	The Moon Wave (PA220) and Mini Moon (PA221) Electric Breast Pump is a personal use, electrically powered device used to express milk from the breasts of lactating women. This device is not intended for hospital use	The Moon Wave (PA220) and Mini Moon (PA221) Electric Breast Pump is a personal use, electrically powered device used to express milk from the breasts of lactating women. This device is not intended for hospital use
User Population	Lactating women	Lactating women	Lactating women
Environment of Use	Home	Home	Home
Power Source	AC adapter or rechargeable battery	12V DC adapter or 7.4V Li-ion battery	5V/2A USB-C adapter or 3.7V Li-ion battery
Operating Modes	Stimulation and expression modes	Stimulation and expression modes	Stimulation and expression modes
Suction Level Range	Double Pumping: 85-250mmHg	Stimulation: 45–124 mmHg; Expression: 45–251 mmHg	Stimulation: 45–124 mmHg; Expression: 45–251 mmHg
Pumping Option	Single/double	Single/double	Single/double
Cycling/Suction Control Mechanism	Microcontroller	Microcontroller	Microcontroller
Cycle Speed (CPM)	Up to 100	Up to 120	Up to 111
Pump Type	Diaphragm type	Diaphragm type	Diaphragm type

Backflow Protection	Yes	Yes	Yes

The subject devices and the predicate device share the same intended use as single-user, electrically powered breast pumps intended to express and collect milk from lactating women for home use. The devices fall under the same regulatory classification and product code.

From a technological standpoint, the subject and predicate devices incorporate the same fundamental operating principles, including:

- Dual-phase pumping operation (Stimulation and Expression modes)
- Adjustable suction levels
- Diaphragm-based backflow protection (closed system design)
- Electrically powered vacuum generation
- Single-user home-use configuration

The differences between the subject devices and the predicate are limited to design and user interface refinements, including:

- Form factor (countertop configuration versus wearable configuration)
- User interface layout and control design
- Power supply configuration (voltage and adapter differences)
- Suction and cycle speed adjustability ranges

These differences do not change the intended use, and do not raise different questions of safety or effectiveness.

7. Summary of Nonclinical Testing
   Comprehensive nonclinical testing was conducted to verify performance, safety, and compliance with applicable FDA-recognized consensus standards.

   Bench Performance Testing

   - Bench testing was conducted to verify vacuum pressure output and cycle speed performance across the full range of operating settings for the PA220 and PA221 electric breast pumps. Testing evaluated all suction levels (LV1–LV12) and all speed settings, measuring vacuum pressure (mmHg) and cycle speed (cycles per minute, CPM) under continuous operation. Results demonstrated that the devices consistently achieved the target suction levels and cycle speeds within the specified design tolerance of ±10% across both Stimulation mode and Expression mode.

- Confirmation of maximum suction limit (≤ 275 mmHg for PA220)

- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.

- Anti-backflow performance testing was conducted to verify that expressed milk cannot enter the vacuum tubing or pump console during operation. Results demonstrated that the diaphragm effectively prevented reverse flow of liquid into the vacuum pathway, confirming that the anti-backflow mechanism protects the pump system from milk intrusion during use.

- Timer, auto-shut off, battery indicator, and user interface feature verification

All performance testing met predefined acceptance criteria.

Electrical Safety
Evaluated in accordance with:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 (ed. 3.2) – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-11:2015+A1:2020 – Requirements for Medical Electrical Equipment Used in the Home Healthcare Environment

Electromagnetic Compatibility (EMC)
Evaluated in accordance with:

- IEC 60601-1-2:2014+A1:2020
- CISPR 11 Class B, Group 1 emission limits
- FDA guidance document "Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff" (2023)

The devices demonstrated compliance with emissions and immunity requirements.

Battery Safety
The integrated lithium-ion battery packs were evaluated at the pack level in accordance with:

- IEC 62133-2:2017 (including Amendment 1:2021)
- UN 38.3 transportation safety testing (including altitude simulation)

Testing demonstrated protection against electrical, thermal, mechanical, and reduced-pressure hazards.

Biocompatibility
Patient-contacting materials were evaluated in accordance with:

- 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""(2023)

The patient-contacting components of the PA220 and PA221 electric breast pumps contact intact skin and expressed human milk during use, and the device was evaluated as a prolonged-contact, surface device. Biological evaluation addressed the endpoints of cytotoxicity, sensitization, and irritation, consistent with the contact type and duration. The results demonstrated that the materials are biocompatible for their intended use.

Risk Management
Risk analysis was conducted in accordance with ISO 14971:2019. All identified hazards were mitigated to acceptable residual risk levels.

Software Verification and Validation
The software documentation for the PA220 and PA221 devices was reviewed and evaluated at the appropriate level of documentation (Basic) in accordance with FDA guidance document "Content of Premarket Submissions for Device Software Functions" (June 14, 2023).

The software development and documentation were evaluated in accordance with applicable FDA-recognized consensus standards, including:

- IEC 62304:2006+A1:2015 Medical Device Software —Software Life Cycle Processes
- ISO 14971:2019 — Medical Devices — Application of Risk Management to Medical Devices

8. Conclusion
Based on the provided non-clinical testing, the PA220 and PA221 Electric Breast Pump are as safe and effective as the legally marketed predicate device and support a determination of substantial equivalence.