April 17, 2020

A Cute Baby, Inc.
Matthew Kho
Director
865 N 1430 W
Orem, UT 84057

Re: K200712
Trade/Device Name: Rumble Tuff Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 20, 2020
Received: March 18, 2020

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200712

Device Name
Rumble Tuff Electric Breast Pump

Indications for Use *(Describe)*
The Rumble Tuff Electric Breast Pump is intended to express and collect milk from the breasts of lactating Women. The Rumble Tuff Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by 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 – K200712

1. **Submitter Information:**

A Cute Baby, Inc.
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Tel: 1-801-609-8168
Fax: 1-801-769-2688

Contact: Mr. Matthew Kho
Director
matthew.kho@acutebaby.com

Date of 510(k) Summary prepared: April 16, 2020

2. **Device Information:**

Proprietary Name:	Rumble Tuff Electric Breast Pump
Model Numbers:	PA209DM and PA210DM
Common 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)
Classification Panel:	Obstetrics/Gynecology

3. **Predicate Device Information:**

Predicate Device: Rumble Tuff Electric Breast Pump (K113315)
The predicate device has not been subject to design-related recall.

4. **Device Description:**

The Rumble Tuff electrically powered breast pumps (models PA219DM and PA210DM) are intended for multi-user use to extract milk from lactating breasts. The PA209DM model is powered by a 9V AC/DC Power Adaptor and/or built-in 7.4V Li-Ion battery. The PA210DM model is powered by a 12V AC/DC Power Adaptor and does not have a batter powered option. Pumping can be performed on one breast (single pumping) or on both breasts (double pumping). The pumping system consists of a diaphragm-type vacuum pump which is driven by a microcontroller-controlled DC electric motor. The controlling program consists of 3 phases of speed control (Reflex, Swift, and Natural) and various suction settings. The subject devices utilize an LCD screen as a user interface. All patient-contacting and breast milk-contacting materials are identical to the predicate device.

5. **Indication for Use:**

The Rumble Tuff Electric Breast Pump is intended to express and collect milk from the breasts of lactating women. The Rumble Tuff Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.

6. Comparison of Intended Use and Technological Characteristics:

	Rumble Tuff PA209DM, PA210DM (K200712) (New Devices)	**Rumble Tuff PA201D (K113315) (Predicate Device)**
Device Name	Rumble Tuff Electric Breast Pumps (PA209DM, PA210DM)	Rumble Tuff Electric Breast Pump – PA201D
Indication for Use	The Rumble Tuff Electric Breast Pump is intended to express and collect milk from the breasts of lactating women. The Rumble Tuff Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.	The Rumble Tuff 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.
Environment of Use	Hospital, Home	Home
Vacuum Range	75 – 250 mmHg	85 – 250 mmHg
Power Supply	**PA209DM** - 9V AC/DC Adapter, 7.4V Li-Ion Rechargeable battery, **PA210DM** - 12V AC/DC Adapter	12V AC/DC Adapter 7.4V Li-ion Rechargeable battery
Pumping Option	Single/double	Single/double
Cycling/ Suction Control Mechanism	Microcontroller	Microcontroller
Backflow Protection	Silicone Diaphragm	Silicone Diaphragm
User control	PA209DM: - Expression Button - Vacuum Adjusting Knob - M Button (memory) - Power (on vs. off) PA210DM: - Vacuum Adjusting Buttons (up and down) - Expression Button - M Button (memory)	Vacuum Adjusting Wheel Let-down Button M button Power (on vs. off)

	- Power (on vs. off)	
Solenoid valve	PA209DM: 1 PA210DM: 2	1
Vacuum range	**AC/DC adaptor powered** Reflex (8 levels): 80 – 211 mmHg Swift (8 levels): 80 – 176 mmHg Natural (10 levels): 81 – 247 mmHg **Battery powered (PA209DM)** Reflex (8 levels): 78 – 206 mmHg Swift (8 levels): 80 – 172 mmHg Natural (10 levels): 79 – 242 mmHg	80 – 250 mmHg
Cycle speed	Reflex: 20 cycles in 15 seconds Swift: 82 – 115 cycles/min Natural: 30 – 76 cycles/min	Stimulation mode: 168 – 100 cycles/min Expression mode: 42 – 74 cycles/min
Material (that may come in contact with the user's body)	Polypropylene for Breast shield; Silicone for Breast shield cover	Polypropylene for Breast shield; Silicone for Breast shield cover
Sterilization	Non-sterile	Non-sterile
Vacuum chamber	2	1
Ambient Temperature range	+10°C to 40°C (50°F to 104°F)	+10°C to 40°C (50°F to 104°F)
Transportation / Storage Environment	**Temperature**: -10 to 50˚c **Relative Humidity**: 20 ~ 90%	**Temperature**: -10 to 50˚c **Relative Humidity**: 20 ~ 80%

The subject and predicate device have similar indications for use and have the same intended use.

The subject and predicate device have different technological features, including a different design, user interface, number of vacuum chambers, number of solenoid valves, number of operation modes, number of vacuum levels, cycle speed/range, and power sources. These technological differences do not raise different questions of

safety and effectiveness.

7. Summary of Non-Clinical Tests:

The subject devices comply with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps. The following data were provided in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with EN ISO 14971:2012.
- Electrical Safety Testing in accordance with IEC 60601-1:2005-1:2005+CORR.2.2007+AM1:2012.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- Safety testing for use in a home setting in accordance with IEC 60601-1-11:2015.
- Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).
- Backflow protection testing
- Vacuum performance testing
- Use life testing

8. Conclusion:

The performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and supports a determination of substantial equivalence.