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.


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.
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
Indications for Use

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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   Food and Drug Administration
   Office of Chief Information Officer
   Paperwork Reduction Act (PRA) Staff
   PRASStaff@fda.hhs.gov

   “An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) Summary – K200712

1. **Submitter Information:**
   A Cute Baby, Inc.
   865 N 1430 W
   Orem, UT 84057 USA
   Tel: 1-801-609-8168
   Fax: 1-801-769-2688

   **Contact:**
   Mr. Matthew Kho
   Director
   [matthew.kho@acutebaby.com](mailto: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 PA209DM 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 battery 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:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Rumble Tuff PA209DM, PA210DM (K200712) (New Devices)</th>
<th>Rumble Tuff PA201D (K113315) (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for Use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>Hospital, Home</td>
<td>Home</td>
</tr>
<tr>
<td>Vacuum Range</td>
<td>75 – 250 mmHg</td>
<td>85 – 250 mmHg</td>
</tr>
<tr>
<td>Power Supply</td>
<td>PA209DM - 9V AC/DC Adapter, 7.4V Li-Ion Rechargeable battery, PA210DM - 12V AC/DC Adapter</td>
<td>12V AC/DC Adapter 7.4V Li-Ion Rechargeable battery</td>
</tr>
<tr>
<td>Pumping Option</td>
<td>Single/double</td>
<td>Single/double</td>
</tr>
<tr>
<td>Cycling/Suction Control Mechanism</td>
<td>Microcontroller</td>
<td>Microcontroller</td>
</tr>
<tr>
<td>Backflow Protection</td>
<td>Silicone Diaphragm</td>
<td>Silicone Diaphragm</td>
</tr>
</tbody>
</table>
| 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) |
<table>
<thead>
<tr>
<th>Solenoid valve</th>
<th>- Power (on vs. off)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA209DM: 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA210DM: 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

- **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

- **Sterilization**
  - Non-sterile

- **Vacuum chamber**
  - 2

- **Ambient Temperature range**
  - +10°C to 40°C (50°F to 104°F)

- **Transportation / Storage Environment**
  - **Temperature:** -10 to 50°C
  - **Relative Humidity:** 20 ~ 90%

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.
- 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.