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3F, No.11, Lane 35, Jihu Road, Neihu Dist., Taipei, Taiwan
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NOV 20 2012

510(K) Summary

Applicant:
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A Cute Baby, Inc.
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Date of Submission: 11/01/2012

Proprietary Name: Rumble Tuff Electric Breast Pump
(Models: PA200S, PA201S, PA201D, PA203S and PA203D)

Common Name: Electric Breast Pump

Classification name: Pump, Breast, Powered

Regulatory Class: Class II

Product Codes: HGX

Indication 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.

Predicate Device(s): Swing Breastpump (K053052) By Medela, Inc. and Lansinoh Affinity Double Electric Breast Pump (DEBP) (K092783) By ENKO Ltd.

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Device Description: The Rumble Tuff Electric Breast Pump is a powered Breast Pump. With different models, the Pumping can be performed on one breast or on both breasts at the same time; the Rumble Tuff Electric Breast Pump can be powered by 4 AA batteries, one 7.4V Li batteries or an AC Adapter provided with the pump. The pumping system consists of a diaphragm-type vacuum pump which is driven by a microcontroller controlled DC electric motor. Rumble Tuff Electric Breast Pump has five models; PA200S, PA201S, PA201D, PA203S, and PA203D. The suffix "S" stands for the model with single collection kit, and "D" stands for the model with dual collection kits. The user interface of PA200S uses 4 LEDs for indicating pumping cycle and uses a roller type adjuster for pumping level adjustment and indicating pumping level. Models PA201S, PA201D, PA203S, and PA203D all use the same user interface, a LCD screen for showing the pumping information; it also uses a roller type adjuster for pumping level adjustment. For all models, the user is able to control the cycle speed and vacuum level. The summary of the 5 models are as follows:

Single Pumping Models

Model	**PA200S**	**PA201S**	**PA203S**
Pumping Suction	125 – 250 mmHg	115 – 250 mmHg	115 – 250 mmHg
Suction Settings	7 Levels	a) Stimulation (8 Levels) b) Expression (8 Levels)	a) Stimulation (8 Levels) b) Expression (8 Levels)
Power Supply	a) 4 AA Alkaline Batteries b) 12V AC/DC Adapter	a) 7.4V Li-Ion Battery b) 12V AC/DC Adapter	a) 4 AA Alkaline Batteries b) 12V AC/DC Adapter
Pumping Option	Single	Single	Single
Back Flow Protection	Yes	Yes	Yes
Interface (display)	LED indicators	LCD Screen	LCD Screen
Pumping Cycles	up to 1.67/sec	Up to 1.83/sec	Up to 1.11/sec

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Double Pumping Models

Model	PA201D	PA203D
Pumping Suction	85 – 250 mmHg	85 – 250 mmHg
Suction Settings	a) Stimulation (8 levels) b) Expression (8 levels)	a) Stimulation (8 levels) b) Expression (8 levels)
Power Supply	a) 7.4V Li-Ion Battery b) 12V AC/DC Adapter	a) 4 AA Alkaline Batteries b) 12V AC/DC Adapter
Pumping Option	Single or Double	Single or Double
Back Flow Protection	Yes	Yes
Interface (display)	LCD Screen	LCD Screen
Pumping Cycles	Up to 1.23/sec	Up to 1.23/sec

Materials Used: The patient-contacting portions of the Rumble Tuff Electric Breast Pump are composed of polypropylene and silicone. The patient-contacting portions of the predicate devices also included polypropylene. The polypropylene and silicone in the Rumble Tuff were evaluated for biocompatibility per ISO 10993 (see testing description in the "Testing" section) and deemed biocompatible.

Testing: The Rumble Tuff Electric Breast Pump is tested to meet:

- IEC 60601-1:2005, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-2:2007, "Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. "
- ISO 10993-5: 2009, "In Vitro Cytotoxicity Test of Expression collection Kit"
- ISO 10993-10: 2010, "Skin Sensitization Test of Expression collection Kit (polar and non-polar)"
- ISO 10993-10: 2010, "Skin irritation Test of Expression collection Kit (polar and non-polar)"
- Additionally, the tests of vacuum levels and cycle speeds conducted by Acute Ideas are provided to demonstrate the performance of Rumble Tuff Electric Breast Pump.

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Comparison to Predicate Devices:

The following table summarizes the basic similarities and differences between Rumble Tuff Electric Breast Pump and predicate devices.

For single pumping models:

	New Device	New Device	New Device	Predicate Device
Device Name	Rumble Tuff Electric Breast Pump – PA200S	Rumble Tuff Electric Breast Pump – PA201S	Rumble Tuff Electric Breast Pump – PA203S	Medela Swing
510(k) #	K113315	K113315	K113315	K053052
Product Code	HGX	HGX	HGX	HGX
Classification	2	2	2	2
Intended use	to express milk	to express milk	to express milk	to express milk
Power Source	a) 4 AA alkaline batteries b) 12V AC/DC Adapter	a) 7.4V Li-Ion Rechargeable Battery b) 12V AC/DC Adapter	a) 4 AA Alkaline Batteries b) 12V AC/DC Adapter	a) 4 AA alkaline batteries b) 4.8V DC Adapter
Pump type	Diaphragm type	Diaphragm type	Diaphragm type	Diaphragm type
Pumping Suction	125 – 250 mmHg	115 – 250 mmHg	115 – 250 mmHg	0 - 250 mmHg
Adjustable suction level	Yes	Yes	Yes	Yes
Pumping Option	Single	Single	Single	Single
Back Flow Protection	Yes	Yes	Yes	No
Let Down Function	Yes	Yes	Yes	Yes
Cycling / Suction Control Mechanism	Microcontroller	Microcontroller	Microcontroller	Microcontroller
Design of vacuum relief	Using a vacuum relief valve driven by a solenoid	Using a vacuum relief valve driven by a solenoid	Using a vacuum relief valve driven by a solenoid	Using a vacuum relief valve driven by a solenoid
Material (that may contact user's body)	PP for Breastshield; Silicone for Breastshield cover	PP for Breastshield; Silicone for Breastshield cover	PP for Breastshield; Silicone for Breastshield cover	PP for Breast Shield

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For double pumping models:

	New Device	New Device	Predicate Device
Device Name	Rumble Tuff Electric Breast Pump – PA201D	Rumble Tuff Electric Breast Pump – PA203D	Lansinoh DEBP
510(k) #	K113315	K113315	K092783
Product Code	HGX	HGX	HGX
Classification	2	2	2
Intended use	to express milk	to express milk	to express milk
Power Source	a) 7.4V Li-Ion Rechargeable Battery b) 12V AC/DC Adapter	a) 4 AA Alkaline Batteries b) 12V AC/DC Adapter	a) 6 AA alkaline batteries b) 9V DC Adapter
Pump type	Diaphragm type	Diaphragm type	Diaphragm type
Pumping Suction	85 – 250 mmHg	85 – 250 mmHg	50 - 250 mmHg
Adjustable suction level	Yes	Yes	Yes
Pumping Option	Single or Double	Single or Double	Single or Double
Back Flow Protection	Yes	Yes	Yes
Let Down Function	Yes	Yes	Yes
Cycling/Suction Control Mechanism	Microcontroller	Microcontroller	Microcontroller
Design of vacuum relief	Using a vacuum relief valve driven by a solenoid	Using a vacuum relief valve driven by a solenoid	Using a vacuum relief valve driven by a solenoid
Material (that may contact user's body)	PP for Breastshield; Silicone for Breastshield cover	PP for Breastshield; Silicone for Breastshield cover	PP + TPR for Breast Shield

Conclusion: The Rumble Tuff Electric Breast Pumps are substantially equivalent to the predicate devices. Based upon the test data submitted, the devices provide sufficient vacuum pressure to safely and effectively express and collect milk from lactating women.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Acute Ideas Co., Ltd.
% Mr. Matthew Kho
Director
A Cute Baby, Inc.
865 N 1430 W
OREM UT 84057

Re: K113315
Trade/Device Name: Rumble Tuff® Electric Breast Pump
(Models: PA200S, PA201S, PA201D, PA203S and PA203D)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: November 6, 2012
Received: November 6, 2012

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K113315

Device Name: Rumble Tuff® Electric Breast Pump
(Models: PA200S, PA201S, PA201D, PA203S and PA203D)

Indication for Use:

The Rumble Tuff Electric Breast Pump is an electrically powered single-user device to express and collect milk from the breasts of lactating women. The device is not intended for hospital use.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113315