April 4, 2018

Babyation, LLC
% Allison Komiyama
Principal Consultant
Acknowledge Regulatory Strategies, LLC
2834 Hawthorn Street
San Diego, California 92104

Re: K173699
Trade/Device Name: The Pump by Babyation
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: Class II
Product Code: HGX
Dated: March 1, 2018
Received: March 5, 2018

Dear Allison Komiyama:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173699

Device Name
The Pump by Babyation

Indications for Use *(Describe)*
The Pump by Babyation is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts. The Pump by Babyation can be used by multiple users.

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
K173699

DATE PREPARED
March 14, 2018

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DEVICE INFORMATION

Proprietary Name/Trade Name:	The Pump by Babyation
Common Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Class:	II
Product Code:	HGX (pump, breast, powered)
Review Panel:	Obstetrics/Gynecology

PREDICATE DEVICE IDENTIFICATION

510(k) Number:	K160511
Device Name:	Naya Breast Pump System
Manufacturer:	Naya Health, Inc.
	The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Pump by Babyation is a multiple-user powered breast pump system that allows lactating women to discreetly express and collect milk. It is powered by a rechargeable lithium ion battery. Users have the option of single or double pumping. The device has two phases of pumping, stimulation and expression. Stimulation phase is characterized by faster cycle times and lower suction levels and is used to initiate milk letdown. Expression phase is characterized by slower cycle times and higher suction levels and is used after milk letdown has occurred.

The device consists of a main enclosure which houses all of the electrical components that control the system and the pneumatic components that generate suction at vacuum levels up to 250mmHg. The main enclosure also provides an insulated storage area for one ice pack, milk collection bottles, breast shields, and the necessary tubing for the system. The device also includes a mobile app that connects to the device via Bluetooth and allows the user to control the pump.

INDICATIONS FOR USE

The Pump by Babyation is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts. The Pump by Babyation can be used by multiple users.

PREDICATE COMPARISON

The following table compares The Pump by Babyation to the predicate device with respect to the indications for use and technological characteristics:

Device & Predicate Device	**Subject Device Babyation LLC / The Pump by Babyation (K173699)**	**Predicate Device Naya Health Inc. / Naya Breast Pump System (K160511)**
Indications for Use	The Pump by Babyation is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts. The Pump by Babyation can be used by multiple users.	The Naya Breast Pump System is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts.
Single/Multiple	Multiple users	Multiple users
Environment of Use	Hospital, Home	Hospital, Home
Power Source	Input: 100-240 VAC, 50/60Hz, 0.7-0.35A Rechargeable Li-Ion Battery (7.2 V / 2200 mAh)	Input: 100-240 VAC, 50/60Hz, 2.1A Rechargeable Li-ion Battery (1 x 14.8V / 3200 mAh)
Pump Type	Reciprocating diaphragm pump	Reciprocating diaphragm pump
User Interface	Hardware interface, mobile app	Hardware interface, mobile app
User Control	Power Button Control Wheel / Button Mobile App	Power Button Touch Wheel / Button Mobile App
Software	Yes	Yes
Mobile App	Yes	Yes
Single/double	Both	Both
Adjustable Suction Levels	10 levels	10 levels
Cycle Speed (cycles /min)	30 – 120	34 – 120

Device & Predicate Device	**Subject Device Babyation LLC / The Pump by Babyation (K173699)**	**Predicate Device Naya Health Inc. / Naya Breast Pump System (K160511)**
Backflow Protection (prevention of backflow of liquid into pump/tubing)	Yes (filter, sensor)	Yes (diaphragm)
Overflow Protection (stops pumping when the bottle is full to prevent overflow)	Yes (sensor)	
Vacuum range - double / single (mmHg)	50-250 / 50-250	50-250 / 50-260
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor
Design Features	• Reciprocating diaphragm vacuum pump • Portable, battery powered • Pump controlled by interface on unit or by mobile app • Air-based silicone flange (i.e., breast shield) • Expressed milk flows from the flanges to the bottles through tubing	• Reciprocating diaphragm vacuum pump • Portable, battery powered • Pump controlled by interface on unit or by mobile app • Water-based silicone flange • Milk expressed directly in collection cups attached to the flanges

The Pump by Babyation has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

Non-clinical testing was conducted to verify that The Pump by Babyation met all design specifications, demonstrated safety based on current industry standards, and is substantially equivalent to the predicate. The following tests were performed:

A. Cleaning: The reusable components were subjected to cleaning and reprocessing using methods outlined in AAMI TIR30 A compendium of processes, materials, test methods, and acceptance criteria/or cleaning reusable medical devices.

B. Biocompatibility: Patient contacting material was subjected to biocompatibility testing in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10).

C. Software Verification: The software development and testing was executed with consideration to IEC 62304 Medical device software – Software life cycle processes. Software documentation was provided in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

D. Electromagnetic Compatibility, Electrical Safety, and Battery Safety: The subject device was tested in compliance with the following:

   i. ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

   ii. IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

   iii. IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

   iv. IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

E. Wireless Coexistence: The subject device was tested in compliance with ANSI C63.27 American National Standard for Evaluation of Wireless Coexistence, KDB 447498 RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices

F. Performance Testing: Bench testing was conducted to demonstrate pump performance (vacuum performance, speed verification, milk collection in the worst case scenario), battery performance, backflow control, and cross contamination were tested using internal test protocols.

G. Usability: Usability testing was performed in compliance with IEC 62366 Medical devices - Part 1: Application of usability engineering to medical devices and IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

CLINICAL PERFORMANCE DATA

Not Applicable

CONCLUSION

Based on the comparison and analysis above, The Pump by Babyation is substantially equivalent to the predicate device.