October 13, 2017

DAO Health
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172772
Trade/Device Name: Freemie® Independence and Freemie® Liberty Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: September 13, 2017
Received: September 14, 2017

Dear Mark Job:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172772

Device Name
Freemie® Independence and Freemie® Liberty Breast Pump

Indications for Use *(Describe)*
The Freemie® Independence and Freemie® Liberty are powered breast pumps to be used by lactating women to express and collect milk from their breast. The Freemie® Independence and Freemie® Liberty pumps are intended for 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.

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

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510(k) Summary
Freemie® Independence and Freemie® Liberty Breast Pump

In accordance with 21 CFR 807.92 the following summary of information is provided:

SUBMITTER:

DAO Health
1345 Easy Lane
El Dorado Hills, CA 95762

DATE PREPARED:

July 12, 2017

PRIMARY CONTACT PERSON:

Dave Paul
Phone: 916-339-7388
FAX: 877-869-1973
e-mail: dave@freemie.com

Device:

TRADE NAME: Freemie® Independence and Freemie® Liberty Breast Pump
COMMON NAME: Powered Breast Pump
CLASSIFICATION NAME: Pump, Breast, Powered
REGULATORY CLASS: II
PRODUCT CODE: HGX
REGULATION NUMBER: 884.5160

PREDICATE DEVICE:

Spectra S1 Plus and Spectra S2 Plus Breast Pump (K150476)
The predicate devices have not been subject to a design-related recall.

INDICATIONS FOR USE:

The Freemie® Independence and Freemie® Liberty are powered breast pumps to be used by lactating women to express and collect milk from their breast. The Freemie® Independence and Freemie® Liberty pumps are intended for use by a single user.

DEVICE DESCRIPTION:

The Freemie® Independence and Freemie® Liberty powered breast pumps utilizes the supplied previously cleared device (K130349) Freemie® Breast Pump Collection System to express and collect milk from the breast of a lactating woman. Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time. The system is designed for mobile pumping (home, office, etc.) as the device is light weight, compact in size and can be attached to the user's clothing with a clip.

Ten (10) suction levels, eleven (11) cycle speeds and three (3) memory settings (suction and cycle levels) are user adjustable via tactile switches (referred to as buttons). The pumps are powered by a rechargeable lithium-ion polymer battery which can be charged with a USB to micro USB provided cable (laptop, car, etc.) and alternatively with a supplied wall charge adapter with a USB port for charging the battery with mains power. The sole function of the Micro USB port on the pump is for charging the pump. The power to the pump is always supplied by the battery, even when charging.

Firmware controls a low voltage DC swash plate vacuum pump and solenoid that is capable of providing vacuum levels from -10 to -280 mmHg with cycle speeds from 18 to 150 cycles per minute. A physical barrier on the collection side prevents backflow of milk into the pump.

The Freemie® Independence Pump has a series of LED lights to indicate the pump's current use settings to the user and has a pre-programmed auto shut-off timer that turns the pump off after 40 minutes. The Freemie® Liberty Breast Pump has an LCD screen to indicate the pump's current use settings to the user and has an auto shut-off timer that is user adjustable in five minute increments from 5 to 40 minutes.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE COMPARED TO THE PREDICATE DEVICE

The indications for use of Freemie® Independence and Freemie® Liberty powered breast pumps are the same as the predicate devices. The subject and predicate devices have the same intended use – to express and collect milk from the breast of a lactating woman.

The Freemie® Independence and Freemie® Liberty powered breast pumps generate vacuum in a similar manner as the predicate device and are capable of providing a similar level of vacuum as the predicate device. The subject and predicate devices have similar technological characteristics such as tactile switches, LCD screen, rechargeable lithium-ion polymer battery, adjustable suction and cycle levels, auto shut-off timer, embedded software (firmware) and backflow protection.

Table 1 below identifies key similarities and differences of the proposed Freemie® Independence and Freemie® Liberty to the legally marketed predicated device, the Spectra S1 Plus and Spectra S2 Plus breast pump (K150476).

TABLE 1. COMPARISON OF SUBJECT DEVICE TO PREDICATE DEVICE

	Subject Device	**Predicate Device (K150476)**
GENERAL DEVICE CHARACTERISTICS		
Product Name	Freemie® Independence and Freemie® Liberty	Spectra S1 Plus and Spectra S2 Plus
Manufacturer	DAO Health	Uzinmedicare Co.
Product Code	HGX	HGX
Regulation Number	21 CFR 884.5160	21 CFR 884.5160
Class	II	II
Patient Population	Breastfeeding Women	Breastfeeding Women
Indications for Use	The Freemie® Independence and Freemie®	The Spectra S1 Plus and Spectra S2

	Liberty are powered breast pumps to be used by lactating women to express and collect milk from their breast. The Freemie® Independence and Freemie® Liberty pumps are intended for use by a single user.	Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.
User Interface and Controls		
Pump Options	Single or Double	Single or Double
Power Button	Tactile Switch	Tactile Switch
Suction Levels	10 levels	Massage Mode: 5 levels Expression Mode: 12 levels
Cycle Levels	11 levels	Massage Mode: 1 level Expression Mode: 5 levels
Timer	Fixed auto shut-off (40 minutes for Independence only) Adjustable auto shut-off (5-40 minutes for Liberty only)	Fixed auto shut-off (30 minutes)
Memory Setting	3 user programmable settings	No
Visual Indicator	LED (Independence only) LCD (Liberty only)	LCD
Means of Attaching to Clothing	Clip	No
Charging Port	Micro USB	DC Jack (S1 Plus only)
Specifications		
Pump Type	Swash Plate	Diaphragm
Power Source	100 – 240V AC 50/60 Hz 0.2A Only when using mains with wall power adapter to charge battery	100 – 240V AC 50/60 Hz 600mA (Only when using mains with wall power adapter to charge battery for S1 Plus)
Battery	3.70V/2200mAh Rechargeable Lithium-ion Polymer Battery	11.1V/2000mAh Rechargeable Lithium-ion Polymer Battery (S1 Plus only)
Vacuum Range	-10 to -280 mmHg	-50 to -280 mmHg
Cycle Speed	18 to 150 cycles/minute	38 to 70 cycles/minute
Backflow Protection	Yes	Yes
Software	Embedded	Embedded
Weight	9.2 ounces	42.5 ounces
Size	<4 inches in diameter, <2 inches tall	<8.5 inches in diameter, <6.5 inches tall

The technological characteristics of the subject device that are different – number of suction and number of cycle levels, cycle speed range, auto shut-off timer, and user adjustability of the auto shut-off timer, memory settings, means of attaching the pump to the user's clothing, charging port, weight and size do not raise safety and effectiveness questions by these differences.

SUMMARY OF NON-CLINICAL TESTS:

The Freemie® Independence and Freemie® Liberty powered breast pumps complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment, usability, portable battery safety requirements and photobiological safety of lamps. The following data were provided in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971:2007
- Electrical safety testing in accordance with IEC 60601-1:2005 (2012 reprint)
- Electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014 (4th edition)
- Electrical safety usability testing in accordance with IEC 60601-1-6:2010 (3rd edition) +

A1:2013

- Electrical safety testing for use in home in accordance with IEC 60601-1-11:2015 (2nd edition)
- Safety testing for portable sealed secondary cells and batteries made from them in accordance with IEC 62133:2012 (2nd edition)
- Photobiological safety testing of lamps in accordance with IEC 62471:2006 (1st edition)
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)
- Performance testing to determine minimum and maximum vacuum levels and cycle speeds, backflow protection (fill test), motor life cycle, drop test, voltage verification and Spectra S1 Plus and S2 Plus comparison testing.
- Biocompatibility: the subject device (the pump itself) does not have direct or indirect user contact. The subject device utilizes the supplied previously cleared device (K130349) Freemie® Breast Pump Collection System.

CONCLUSION:

The differences between the Freemie® Independence and Freemie® Liberty powered breast pumps and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Based on non-clinical testing, DAO Health concludes that the Freemie® Independence and Freemie® Liberty powered breast pumps perform as intended and are substantially equivalent to the legally marketed predicate device, the Spectra S1 Plus and Spectra S2 Plus.