March 16, 2023

MilkMate Products, Inc.
% Adrienne Lenz
Principal Medical Device Regulatory Expert
Hymann, Phelps & McNamara P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005

Re: K223084
Trade/Device Name: MilkMate Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 17, 2023
Received: February 17, 2023

Dear Adrienne Lenz:

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 -S

Monica D. Garcia, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223084

Device Name
MilkMate Breast Pump

Indications for Use *(Describe)*
The MilkMate Breast Pump is intended to be used by lactating women to express and collect milk from their breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. It is intended for multiple users in places of work, shared spaces, healthcare facilities, hospitals, and the home.

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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K223084

510(k) Summary

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

DATE: March 16, 2023

SUBMITTER:

MilkMate Products Inc.
41 Purdy Ave
Box #1052
Rye, NY 10580

PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

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DEVICE INFORMATION:

DEVICE/TRADE NAME: MilkMate Breast Pump
COMMON/USUAL NAME: Powered breast pump
REGULATION NUMBER: 21 CFR 884.5160
REGULATION NAME: Powered breast pump
REGULATORY CLASS: II
PRODUCT CODE: HGX (Pump, Breast, Powered)
REVIEW PANEL: Obstetrics/Gynecology

PREDICATE DEVICE:

Electric Breast Pump, Model XN/MS-2224B (K201152)

The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:

The MilkMate Breast Pump includes a multi-user breast pump and disposable breast pump kits for the convenience of pumping in the workplace, shared spaces, healthcare facilities, hospitals, or the home environment.

The breast pump provides two modes: stimulation and expression mode. It can be operated using AC power or a built-in rechargeable li-ion cylindrical battery.

The kits are comprised of two each of a breast shield, breast shield body, backflow protector, valve and membrane, standard neck bottle pouch with cap, tubing, and tubing connector. Three breast shield sizes are offered (27 mm, 30 mm, and 36 mm). The kits are pre-assembled and sterile.

INDICATION FOR USE:

The MilkMate Breast Pump is intended to be used by lactating women to express and collect milk from their breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. It is intended for multiple users in places of work, shared spaces, and the home.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The table below compares the intended use and technological characteristics of the subject and predicate device

	Subject Device **MilkMate Breast Pump**	**Predicate Device** **Electric Breast Pump** **Model XN/MS-224B** **(K201152)**
General Device Characteristics		
Product Name	MilkMate Breast Pump	Electric Breast Pump, Model XN/MS-2224B

	Subject Device MilkMate Breast Pump	Predicate Device Electric Breast Pump Model XN/MS-224B (K201152)
Manufacturer	Guangdong Horigen Mother & Baby Products Co., Ltd.	Guangdong Horigen Mother & Baby Products Co., Ltd.
US Distributor	MilkMate Products Inc.	Not applicable
Product Code	HGX	HGX
Regulation No.	21 C.F.R. § 884.5160	21 C.F.R. § 884.5160
Class	Class II	Class II
Patient Population	Lactating women	Lactating women
Indications for Use	The MilkMate Breast Pump is intended to be used by lactating women to express and collect milk from their breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. It is intended for multiple users in places of work, shared spaces, healthcare facilities, hospitals and the home.	The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. It is intended for a single user in a home or hospital environment.
Intended Use	To express and collect breast milk.	To express and collect breast milk.
Environment of Use	Places of work, shared spaces, healthcare facilities, hospitals and the home.	Hospital, Home

	Subject Device **MilkMate Breast Pump**	**Predicate Device** **Electric Breast Pump** **Model XN/MS-224B** **(K201152)**
User Interface		
User Control	Buttons to control • Vacuum Setting • Cycle Speed Setting • Mode of Operation • User Mode • Alarm Clock • Switch/Pause • Child Lock • Night Light Lithium Battery Power Switch	Buttons to control • Vacuum Setting • Cycle Speed Setting • Mode of Operation • User Mode • Alarm Clock • Switch/Pause • Child Lock • Night Light Lithium Battery Power Switch
Visual Indicator	LED display indicates • Vacuum Setting • Cycle Speed Setting • Mode of Operation • Pump Operating Time • Battery Status	LED display indicates • Vacuum Setting • Cycle Speed Setting • Mode of Operation • Pump Operating Time • Battery Status
Night Light	LED light with two lighting levels	LED light with two lighting levels
Modes of Operation	Stimulation, Expression	Stimulation, Expression
Single/Double Pumping	Single or Double	Single or Double

	Subject Device **MilkMate Breast Pump**	**Predicate Device** **Electric Breast Pump** **Model XN/MS-224B** **(K201152)**
Cleaning – Multi-User Pump Unit	The pump body should be wiped down with a clean paper towel or soft cloth after each use.	The pump body should be wiped down with a clean paper towel or soft cloth after each use.
Technological Characteristics		
Pump Type	Diaphragm	Diaphragm
Suction Levels	7 Levels Stimulation 12 Levels Expression	7 Levels Stimulation 12 Levels Expression
Suction Strength	Across all breast shield sizes (27, 30, and 36 mm) Stimulation: • Single -37.5 to -165 ±30 mmHg • Double -15 to -90 +15/-30 mmHg Expression: • Single -37.5.5 to -232.5 ±30 mmHg • Double -15 to -187.5 +15/-30 mmHg Maximum: -262.5 mmHg	With Horigen 25 mm 3D breast shield Stimulation: • Single -37.5 to -187.5 ±20 mmHg • Double -15 to -105 +15/-20 mmHg Expression: • Single -75 to -247.5 ±20 mmHg • Double -15 to -225 +15/-20 mmHg Maximum: -267.5 mmHg
Cycle Speed	3 Levels Stimulation, 70 – 105 cycles/minute 6 Levels Expression, 34-54 cycles/min	3 Levels Stimulation, 70 – 105 cycles/minute 6 Levels Expression, 34-54 cycles/min
Power Supply **(Conventional Outlet)**	AC/DC wall converter Input 100V – 240V, 50/60Hz Output : 15V, 1.6A	AC/DC wall converter Input 100V – 240V, 50/60Hz Output : 15V, 1.6A

	Subject Device **MilkMate Breast Pump**	**Predicate Device** **Electric Breast Pump** **Model XN/MS-224B** **(K201152)**
Power Supply **(Battery)**	Rechargeable Lithium Ion Battery 11.1V 2000mAh Li-ion Cylindrical Battery	Rechargeable Lithium Ion Battery 11.1V 2000mAh Li-ion Cylindrical Battery
Back Flow Protection	Yes, provided by diaphragm backflow protector in kit	Yes, provided by diaphragm backflow protector in kit
Software	Yes	Yes
Electrical Protection Type	Class II and/or internally powered equipment	Class II and/or internally powered equipment
Degree of protection against electric shock	Type BF applied parts	Type BF applied parts
Electrical Mode of Operation	Continuous	Continuous
Breast Pump Kit		
Components	• Breast shield (27 mm, 30 mm, 36 mm) • Breast shield body • Backflow protector (diaphragm, top cap and bottom cap) • Valve and membrane • 200 mL pouch with cap • Tubing • Tubing connector	• Dust cover • Silicone cushion • Breast shield body • Backflow protector (diaphragm, cap) • 120 ML bottle with cap • Bottle stand • Tubing • Tubing connector • Bottle adaptor • Nipple • Disc collar • Nipple dust cover
Cleanliness	Milk collection kit is Ethylene oxide sterilized	Clean prior to first use. Clean after every use.

The indications for use of the subject and predicate device are similar, with minor differences related to intended use population (single vs. multiple users) and environment of use (home, hospital, workplace, shared spaces, and healthcare facilities vs home, and hospital). The subject device and the predicate device have the same intended use: to express and collect milk from a lactating woman's breast.

The subject and predicate device have similar technological features, including identical pump and pump settings (vacuum settings, cycle speed, battery life, and use-life). The subject device differs from the predicate device in suction strength and the use of a single use ethylene oxide sterilized kit. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness, as these differences can be assessed by the performance testing outlined below.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Pump hardware and software testing were leveraged from K201152. There are no differences in the pump hardware and software between the MilkMate Breast Pump and predicate device.

The following data were provided in support of the substantial equivalence determination:

- Biocompatibility testing of the sterile kits was performed for endpoints recommended in the FDA guidance *"Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*.
    - Cytotoxicity per ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
    - Sensitization per ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
    - Irritation per ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- The ethylene oxide sterilization process used for the MilkMate kit was developed and validated for a sterility assurance level of 10^{-6} per ISO11135: 2014, ISO 11737-1: 2006 and ISO11737-2: 2019.
- Testing per ISO 10993-7: 2008 was performed on the MilkMate kits to demonstrate acceptable levels of EO residue and Ethylene Chlorohydrin (ECH) residue.

- Accelerated aging tests per ASTM-F1980:2021 were performed to support a 1-year shelf life. At the end of the accelerated aging time, package integrity was evaluated.

- After accelerated aging, packaged kits were preconditioned in atmospheric conditions and subjected to simulated handling and transportation. After pre-conditioning and simulated transportation and handling, the kits were tested to demonstrate acceptability of the packaging to maintain the sterility of the MilkMate Kits over the shelf-life.

- Vacuum and cycle testing were completed to demonstrate the performance of the MilkMate breast pump and kits. Testing covered:
    - The full range of kit sizes,
    - Both fresh kits and kits that were at the end of the shelf-life,
    - Both single and double pumping,
    - Low, middle, and high vacuum pressures,
    - Low, middle, and high cycle settings,
    - Battery and AC power, and
    - Stimulation and expression modes

- Leak testing was completed using methods described in ASTM F2096-11 to demonstrate that the pouch maintains its integrity throughout the shelf-life.

- To support use by multiple users, backflow testing was performed to demonstrate that the breast pump anti-backflow design works as intended with the disposable kits when the milk collection bottle is full in both stimulation and expression modes.

CONCLUSION:

The results of the performance testing described above demonstrate that the MilkMate Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.