July 12, 2024

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

Re: K241705
Trade/Device Name: MilkMate Breast Pump (A0006);
MilkMate Kit (sterile, single-use only),
21 mm breast shield (A0005-21);
MilkMate Kit (sterile, single-use only),
24 mm breast shield (A0005-24)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 11, 2024
Received: June 13, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K241705

Device Name
MilkMate Breast Pump (A0006);
MilkMate Kit (sterile, single-use only), 21 mm breast shield (A0005-21);
MilkMate Kit (sterile, single-use only), 24 mm breast shield (A0005-24)

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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510(k) Summary – K241705

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

DATE: July 12, 2024

SUBMITTER:

MilkMate Products Inc.
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Rye, NY 10580

PRIMARY 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:

MilkMate Breast Pump (K223084)

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. Five breast shield sizes are offered (21 mm, 24 mm, 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.

	Modified MilkMate Breast Pump	**Predicate MilkMate Breast Pump (K223084)**
General Device Characteristics		
Product Name	MilkMate Breast Pump	MilkMate Breast Pump
Manufacturer	Guangdong Horigen Mother & Baby Products Co., Ltd.	Guangdong Horigen Mother & Baby Products Co., Ltd.
US Distributor	MilkMate Products Inc.	MilkMate Products Inc.
Product Code	HGX	HGX
Regulation No.	21 C.F.R. § 884.5160	21 C.F.R. § 884.5160
Class	Class II	Class II

	Modified MilkMate Breast Pump	Predicate MilkMate Breast Pump (K223084)
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 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.
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.	Places of work, shared spaces, healthcare facilities, hospitals, and the home.
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

	Modified MilkMate Breast Pump	Predicate MilkMate Breast Pump (K223084)
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
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 (21, 24, 27, 30, and 36 mm) Stimulation: • Single -37.5 to -165 ±30 mmHg • Double -15 +15/-30 to -105 ±30 mmHg Expression: • Single -37.5.5 to -232.5 ±30 mmHg • Double -15 +15/-30 to -195 ±30 mmHg Maximum: -262.5 mmHg	Across all breast shield sizes (27, 30, and 36 mm) Stimulation: • Single -37.5 to -165 ±30 mmHg • Double -15 +15/-30 to -90 ±30 mmHg Expression: • Single -37.5.5 to -232.5 ±30 mmHg • Double -15 +15/-30 to -187.5 ±30 mmHg Maximum: -262.5 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

	Modified MilkMate Breast Pump	Predicate MilkMate Breast Pump (K223084)
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
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
Breast Pump Kit		
Components	• Breast shield (21 mm, 24 mm, 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	• 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
Cleanliness	Ethylene oxide sterilized	Ethylene oxide sterilized

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 levels, cycle speed, battery life, and use-life). The subject device differs from the predicate device in the available sizes of the breast pump 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:

There are no differences in the pump hardware and software between the MilkMate Breast Pump and predicate device. The MilkMate Breast Pump was modified to include two new breast pump kit sizes: 21 mm and 24 mm. Other than the breast shield component, all other components of the breast pump kits, the materials, and sterilization are identical to the predicate device.

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

- Vacuum and cycle testing were completed to demonstrate the performance of the MilkMate breast pump and new kits. Testing covered:
    - The size 21 mm and 24 mm kits,
    - 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

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.