April 10, 2026

Medela, LLC
Jenni Vescovo
Global Director of Regulatory Affairs
Mom & Baby, Maternity Care & NICU
1101 Corporate Drive
Mchenry, IL 60050

Re: K253510
Trade/Device Name: Freestyle™ Mini Hands-free breast pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 2, 2025
Received: December 2, 2025

Dear Jenni Vescovo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K253510

Device Name
Freestyle™ Mini Hands-free breast pump

Indications for Use *(Describe)*
The Freestyle™ Mini Hands-free breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle™ Mini Hands-free breast pump is intended for a single user.
The breast pump is intended to be used in a home environment.

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 – K253510

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

## 1.0 Submitter's Information

Name: Medela LLC
Address: 1101 Corporate Drive, McHenry, IL 60050, USA
Tel: +1 815-578-2423
Contact: Jenni Vescovo
Email: jenni.vescovo@medela.com

Date of Preparation: April 9, 2026

## 2.0 Device Information

Trade/Device name: Freestyle™ Mini Hands-free breast pump
Common name: Powered Breast Pump
Regulation name: Powered Breast Pump
Regulation number: 21 CFR 884.5160
Classification: Class II
Product code: HGX (Pump, Breast, Powered)

## 3.0 Predicate Device

510(k) number: K241322
Trade name: Electric Breast Pump
Manufacturer: JOYTECH Healthcare Co.,Ltd.

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

## 4.0 Device Description

The Freestyle™ Mini Hands-free breast pump is an electric breast pump intended for use in a home environment by a single user. The device is provided non-sterile and it is not intended to be sterilized. The device is intended for reuse following validated reprocessing procedures as outlined in the instructions for use/user manual. The device supports use on both breasts simultaneously (double pumping).

The device consists of a pump unit and two wearable Hands-free Collection Cups

(consisting of breast shields with O-ring, membranes, inserts (for optional use), and outer shells), connected via tubing. The user interface includes four buttons to power the device on/off, switch between the two phases of pumping (Stimulation and Expression) and adjust (respectively increase/decrease) the vacuum level within each phase (9 levels available in each phase).

The pump is powered by an internal, non-replaceable, rechargeable lithium-ion battery and is charged using the provided USB-C cable. A power adaptor is not included as part of the product configuration (specifications are provided in the instructions for use). The device cannot be operated while connected to a charging source.

The Freestyle™ Mini Hands-free breast pump utilizes a microcontroller and embedded software to control a DC motor and solenoid, generating a cyclic vacuum to express breast milk. During operation, the motor incrementally draws air out of the pump to generate negative pressure. Milk is expressed when the vacuum is applied to the breast and released through an internal valve system. The cycle repeats to maintain milk flow. All components in contact with breast milk are made from materials compliant with applicable food-contact requirements (21 CFR Part 177).

## 5.0 Indication for Use Statement

The Freestyle™ Mini Hands-free breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle™ Mini Hands-free breast pump is intended for a single user. The breast pump is intended to be used in a home environment.

## 6.0 Intended Use and Technological Characteristic Comparison Table

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

| | **Subject Device**<br>**K253510** | **Predicate Device**<br>**K241322** |
|---|---|---|

| | | |
|---|---|---|
| Legal Manufacturer | Medela LLC<br>1101 Corporate Drive McHenry, IL 60050 USA | JOYTECH Healthcare Co.,Ltd. |
| Product name | Freestyle™ Mini Hands-free breast pump | Electric Breast Pump |
| Product code | HGX | HGX |
| Intended Use | Express and collect breast milk | Express and collect breast milk |
| Indications for Use | The Freestyle™ Mini Hands-free breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle™ Mini Hands-free breast pump is intended for a single user. The breast pump is intended to be used in a home environment. | The Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Electric Breast Pump is intended for a single user. |
| Single User Device | Yes | Yes |
| Environment of Use | Home | Home |
| Sterility | Not sterile | Not sterile |
| User Control | 4-button interface: On off/pause, let-down, increase vacuum, decrease vacuum | On / Off button, Mode button (Stimulation/Expression), Suction Increase button, Suction Decrease button |
| Visual Indicators | LED display | LED light |
| Pumping Options | Double pumping | Single or double pumping |
| Adjustable Suction Levels | Yes | Yes |
| User Skin Contact | Breast shields and inserts | Flange |
| Power Supply | Rechargeable Li-Ion battery | 3.7V Li-ion Battery and mains powered for charging |
| Software | Embedded | Embedded |
| 2-phase | Yes | Yes |

| | **Subject Device**<br>**K253510** | **Predicate Device**<br>**K241322** |
|---|---|---|
| Expression | | |
| Cycling Control Mechanism | Microcontroller | Microcontroller |
| Suction Settings (Vacuum Levels) | 9 in Expression,<br>9 in Stimulation | 9 in Expression,<br>6 in Stimulation |
| Vacuum Range | Stimulation:<br>-52 to 161 (±20) mmHg<br>Expression:<br>-70 to -270 (±20) mmHg | Stimulation: 40-100 (±30) mmHg<br>Expression: 50-290 (±30) mmHg |
| Cycle Speed (cpm) | Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level) (±5)<br>Stimulation: 111 (±5%) | Expression: 20-65 (±5)<br>Stimulation: 80-120 (±5) |
| Backflow Protection | Yes | Yes |

The indications for use of the subject and predicate device are the same, and both devices have the same intended use (i.e., for the collection of breast milk from the breasts of lactating women).

The subject and predicate devices are similar in terms of technological characteristics. They share similar microcontroller-based cycling control mechanism and are capable of double pumping. They both incorporate adjustable vacuum levels with settings for both Stimulation and Expression phases and offer similar cycles per minute ranges. Additionally, both devices feature a 4-button interface (On/Off/Pause, Let-down, Increase Vacuum, Decrease Vacuum) and a media separation (backflow protection).

The subject and predicate devices differ in their vacuum performance specifications, with the predicate device achieving a maximum nominal vacuum of 290 mmHg and the subject device achieving 270 mmHg.

The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

## 7 . 0 Summary of Non-Clinical Testing

### Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components of the Freestyle™ Mini Hands-free breast pump was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process".

### Electrical Safety

Testing was conducted in accordance with:

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,
- IEC 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems,
- IEC 60601-1-11 Edition 3.1 2020-07 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.

### Electromagnetic Compatibility

Testing was conducted in accordance with IEC 60601-1-2:2014+A1: 2020 Medical Electrical Equipment - Part 1-2: “General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.”

**Software**

Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document “Content of Premarket Submissions for Device Software Functions.”

**Performance Testing**

The Freestyle™ Mini Hands-free breast pump underwent a comprehensive suite of non-clinical performance tests to support the determination of substantial equivalence to the predicate device. All tests were performed on production-equivalent units, and each test followed predefined protocols and acceptance criteria.
The following evaluations were conducted:

• Vacuum Pressure and Cycle Frequency Testing: Assessed both stimulation and expression modes to verify vacuum levels and cycle speeds remained within specified ranges across all nine user-selectable levels.

• Backflow Prevention Testing: Verified the integrity of the closed fluid pathway and confirmed that milk does not enter the tubing or motor housing under representative use conditions.

• Battery Indicator and LED Display Testing: Confirmed that the battery status display and charging indicator lights accurately reflect real-time power conditions during charging and discharging states.

• Battery Runtime and Charging Time: Evaluated discharge duration and charging cycle performance to ensure sufficient operational time and safe recharging.

• Automatic Shutdown Testing: Validated the system’s ability to auto-shut off after continuous operation for 30 minutes.

• Durability and Use-Life Testing: Simulated extended operational use and repeated cycling to verify sustained performance for 300 hours of use.

**8.0 Conclusion**

The results of the performance testing described above demonstrate that Freestyle™

Mini Hands-free breast pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.