September 18, 2025

Medela AG
% Tiana Steinhoff
Global Regulatory Affairs Manager
Medela LLC
1101 Corporate Drive
McHenry, IL 60050

Re: K251377
Trade/Device Name: Magic InBra™
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 2, 2025
Received: August 18, 2025

Dear Tiana Steinhoff:

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.

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251377

Device Name
Magic InBra™

Indications for Use *(Describe)*
The Magic InBra™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.

The Magic InBra™ powered 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.

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510(k) Summary – K251377

In accordance with 21 C.F.R. §807.92(a) the following summary of information is provided:

1.	**Date Summary Prepared:**	September 17, 2025
2.	**Submitter / Applicant:**	Medela AG Lättichstrasse 4b 6304 Baar Switzerland
3.	**Primary Contact Person:**	Tiana Steinhoff Medela AG Global Regulatory Affairs Manager Phone: +41415621609 Email: tiana.steinhoff@medela.com
	Secondary Contact Person:	Jenni Vescovo Medela LLC Global Director of Regulatory Affairs Mom & Baby, NICU & Maternity Care Phone: +18155782423 Email: jenni.vescovo@medela.com
4.	**Device Information:**	**Trade/Device Name**: Magic InBra™ **Common Name:** Powered Breast Pump **Regulation Number:** 21 CFR 884.5160 **Regulation Name:** Powered Breast Pump **Regulatory Class**: II **Product Code**: HGX (Pump, Breast, Powered)
5.	**Predicate Device Information:**	K200508 Manufacturer: Medela LLC Device Name: Pump In Style® The predicate device has not been subject to a design related recall.

6. **Device Description:**

The Magic InBra wearable breast pump is a single user pump to be used by lactating women to express and collect milk from their breasts in the home environment.

Magic InBra is designed to fit most breast shapes and nursing bras allowing hands-free pumping. The pump is intended to be used by a single user for pumping on one

breast with one Magic InBra breast pump or on both breasts at the same time with two Magic InBra breast pumps.

An optional smartphone application (app) for iPhone and Android, called “Medela Family Pump Control”, connects to the breast pump via Bluetooth and, once connected, allows the user to control the breast pump remotely.

7. **Indications for Use:**

The Magic InBra™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.

The Magic InBra™ powered breast pump is intended for a single user.

This breast pump is intended to be used in a home environment.

8. **Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device:**

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

Characteristic	Predicate Device Medela Pump In Style® (K200508)	Subject Device Medela Magic InBra™
510(k) number	K200508	K251377
Regulation Number	21 CFR 884.5160	21 CFR 884.5160
Regulatory Description	Powered Breast Pump	Powered Breast Pump
Regulatory Class	Class II	Class II
Product Code	HGX	HGX
Indications for Use	Pump In Style® is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This powered breast pump is intended for a single user and is intended to be used in a home environment.	The Magic InBra™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Magic InBra™ powered breast pump is intended for a single user. This breast pump is intended to be used in a home environment.
Single User Device	Yes	Yes
Provided non-sterile	Yes	Yes
Single / Double Pumping	Single or double pumping (with one pump motor unit)	Single or double pumping (with two pump motor units)
Patient Population	Lactating women	Lactating women
Environment of Use	Home	Home

Characteristic	Predicate Device Medela Pump In Style® (K200508)	Subject Device Medela Magic InBra™
Over the Counter (OTC)	Yes	Yes
Power Source	Mains powered or Battery powered (AA rechargeable or alkaline)	Battery powered (internal rechargeable Li-ion battery)
Control Mechanism	Microcontroller	Microcontroller
Mode of operation	Continuous	Continuous
Technological principle to generate vacuum	Air filled	Liquid filled
2-Phase Expression	Stimulation Expression	Stimulation Expression
Cycle speed (cpm)	45 to 111	45 to 110 (±7)
Adjustable Suction Levels	Yes	Yes
Suction levels	10	10
Vacuum range (mmHg)	-50 to -295	Stimulation: -60 to -110 (±15) and -135 to -160 (±20) Expression (first two minutes): -75 to -175 (±15) and -200 to -300 (±20) Expression (remaining session): -75 (+25/-40), -100 to -275 (±40) and -300 (+40/-25)
Backflow Protection	Yes	Yes
Breast shields in different sizes	Yes	Yes
User Interface	4 buttons on the pump body	6 buttons on the pump body
Memory function	No	Yes
Wireless technology / Bluetooth Low Energy	No	Yes
Mobile Application	No	Yes (optional)
Software	Yes	Yes
Overall design	Portable	Wearable
Ingress Protection (IP)	IP22	IP22
Direct user / tissue contact	Yes	Yes

The indications for use of the subject and predicate device are similar, 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 device have different technological characteristics, including different vacuum and cycle specifications,

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

9. Summary of Non-Clinical Tests:

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

Electrical Safety
Electrical Safety Testing was conducted in accordance with IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical Electrical Equipment - Part 1: General requirements for Basic Safety and Essential Performance.

Electrical safety testing for use in home was conducted in accordance with IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, *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
Electromagnetic Compatibility Testing was conducted in accordance with IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, *Medical electrical equipment - Part 1-2: General requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.*

Biocompatibility Evaluation
Biocompatibility Evaluation was completed according to the FDA Guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 2023)”

Software/Firmware Verification and Validation
Software/Firmware Verification and Validation is provided in accordance with the FDA Guidance document “Content of Premarket Submissions for Device Software Functions” (June 2023).

Cybersecurity
Cybersecurity information was provided in accordance with recommendations in the 2023 FDA guidance document, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

Performance Testing

Bench performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the pump motor unit.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator functions as intended.

10. Conclusion:

The results of the performance testing described above demonstrate that Magic InBra™ is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.