January 22, 2026

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

Re: K253498
Trade/Device Name: Pump In Style® Pro+
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: December 23, 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 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
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)*
K253498

Device Name
Pump In Style® Pro+

Indications for Use *(Describe)*
The Pump In Style® Pro+ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The powered breast pump is intended for a single user. This 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 – K253498

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

1.0 Date of Preparation

January 22, 2026

2.0 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

3.0 Device Information

Trade/Device name: Pump In Style Pro+
Common name: Powered breast pump
Regulation name: Powered Breast Pump
Regulation number: 21 CFR 884.5160
Product code: HGX (Pump, Breast, Powered)
Regulatory Class: Class II
Panel: Obstetrics/Gynecology

4.0 Predicate Information

Predicate device
Manufacturer: Medela LLC
Trade/Device Name: Pump In Style
510(k) number: K200508

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

5.0 Device Description

Pump In Style Pro+ is a powered breast pump intended to be used in a home environment (or similar such as an office). It features 2-Phase Expression technology, which runs pumping in two phases (Stimulation and Expression) by applying a cyclic negative pressure to mimic a baby's natural nursing rhythm.

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Pump In Style Pro+ comprises a pump unit, which includes:

- User-adjustable controls: “On/Off” for powering on/off the device, “Let-down" for switching between pumping phases, and “Increase vacuum”/ “Decrease vacuum” for controlling vacuum intensity levels;
- a port for connection of the tubing that channels the vacuum;
- a port for connection of the power supply;
- an internal, non-replaceable, rechargeable lithium-ion battery providing users the option to power the breast pump without reliance on a wall-connection or external power source;
- a LED battery status indicator which informs users of available charge;
- a pump phase LED status indicator which informs users of the active pump phase;
- vacuum level LED indicators (total of 16, one for each vacuum level).

Pump In Style Pro+ is a double electric breast pump that can be used to extract breast milk from one breast at a time (i.e., single pumping) or from both breasts simultaneously (i.e., double pumping). A DC (direct current) motor is used to drive a membrane aggregate. This membrane aggregate creates the negative pressure (suction) required to extract the breast milk.

The materials of the milk-contacting components are compliant with 21 CFR 177 and 21 CFR 178.

6.0 Indications for Use

The Pump In Style Pro+ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The powered breast pump is intended for a single user. This breast pump is intended to be used in a home environment.

7.0 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.

	Pump In Style® (Predicate Device) – K200508	Pump In Style® Pro+ (Subject Device) – K253498
Legal Manufacturer	Medela LLC 1101 Corporate Drive McHenry, IL 60050 USA	Medela LLC 1101 Corporate Drive McHenry, IL 60050 USA
Product name	Pump In Style®	Pump In Style® Pro+

	Pump In Style® (Predicate Device) – K200508	Pump In Style® Pro+ (Subject Device) – K253498
Product code	HGX	HGX
Intended Use	Express and collect breast milk	Express and collect breast milk
Indications for Use	The Pump In Style® breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Pump In Style® breast pump is intended for a single user. The breast pump is intended to be used in a home environment.	The Pump In Style® Pro+ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The powered breast pump is intended for a single user. This breast pump is intended to be used in a home environment.
Contra-indications	None	None
Single User Device	Yes	Yes
Environment of Use	Home	Home
Sterility	Not sterile	Not sterile
User Control	•DC input terminal/ power port • 4-button interface: On/Off, Let-Down, Increase vacuum, Decrease vacuum button • Integral tubing port for double- or single- pumping	• DC input terminal/ power port • 4-button interface: On/Off, Let-Down, Increase vacuum, Decrease vacuum button • Integral tubing port for double- or single- pumping
Visual Indicators	No visual indicators	Yes, LED for current vacuum level, battery status and pumping mode/phase (Stimulation and Expression)
Pumping Options	Single or double pumping	Single or double pumping
Adjustable Suction Levels	Yes	Yes
User Skin Contact	Breast shields	Breast shields
Power Supply	Direct Plug in: Power Supply/mains External Battery pack: AA batteries (Alkaline, Ni-MH)	Direct Plug in: Power Supply/mains Internal Battery: Rechargeable Li-ion
Software	Embedded	Embedded
Electrical	Class II (double insulated)	Class II (double insulated)

	Pump In Style® (Predicate Device) – K200508	Pump In Style® Pro+ (Subject Device) – K253498
Insulation Class		
IP-Protection	IP-22	IP-22
Protection Type	BF	BF
Vacuum aggregate type	Accumulator	Accumulator
2-phase Expression	Yes	Yes
Cycling Control Mechanism	Microcontroller	Microcontroller
Suction Settings (Vacuum Levels)	10	16
Vacuum Range	-50 to -240 mmHg	Stimulation: -60 to -230 mmHg (± 40) Expression: -60 to -255 mmHg (± 40)
Maximum Vacuum Expression	-295 mmHg	-295 mmHg
Cycle Speed	Stimulation: 97 to 140 cycles/minute Expression: 20 to 88 cycles/minute	Stimulation: 100 cycles/minute (+30/-3) Expression: 55 cycles/minute (± 30)
Backflow Protection	Yes - connector with silicone membrane prevents milk backflow into the tubing and pumping mechanism.	Yes (traditional bottle pump set configuration) - connector with silicone membrane prevents milk backflow into the tubing and pumping mechanism. Yes (Hands-free Collection Cups pump set configuration) – silicone membrane prevents milk backflow into the tubing and pumping mechanism.

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 technological differences between the subject and

the predicate device are the number of suction levels, suction level vacuum range, user-interface, the rechargeable Li-ion battery, and replaceable/detachable components of the breast pump (patient-contacting components). These differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

8.0 Summary of Non-Clinical Testing

The following data were provided to support the substantial equivalence determination:

Electrical Safety:
Testing was conducted in accordance with ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601- 1:2005/AMD2:2020) and IEC 60601-1-11:2015 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/AMD1:2020 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software/Firmware Verification and Validation:
Software verification and validation testing as recommended in the 2023 FDA Guidance Document “Content of Premarket Submissions for Device Software Functions.”

Biocompatibility Evaluation:
Biocompatibility testing was leveraged from the predicate device submission in accordance with 2023 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"”.

Non-clinical Performance Testing:
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 conducted at each vacuum level demonstrated that the devices meet vacuum and cycle speed specifications.
• Battery performance testing was conducted to demonstrate that the battery remains

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functional during its stated battery use-life.
• Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.
• Backflow protection testing was conducted to verify liquid does not backflow into the pump motor unit.

9.0 Conclusion

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