February 13, 2026

Medela LLC
Jenni Vescovo
Global Director of Regulatory Affairs
1101 Corporate Drive
McHenry, Illinois 60050

Re: K253149
Trade/Device Name: Motion InBra (YM-8801) wearable breast pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 15, 2026
Received: January 15, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Reginald K. Avery -S

for
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253149

Device Name
Motion InBra (YM-8801) wearable breast pump

Indications for Use *(Describe)*
The Motion InBra (YM-8801) wearable breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Motion InBra (YM-8801) 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.

510(k) Summary – K253149

1. Submitter Information

Applicant: Medela LLC
Phone: 815-363-1166
Address: 1101 Corporate Dr.
McHenry, IL, 60050

2. Correspondent Information

Contact: Jenni Vescovo
Global Director of Regulatory Affairs Mom & Baby, NICU & Maternity Care
Email: jenni.vescovo@medela.com
Phone: (815) 578-2423

3. Date prepared: February 11, 2026

4. Device Information

Device Name:	Motion InBra (YM-8801) wearable breast pump
Common Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Lucy Breast Pump
510(k) Number:	K213311
Manufacturer:	Willow Innovations, Inc.

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

6. Device Description

The Motion InBra (YM-8801) wearable breast pump is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts; it is intended for a single user. The Motion InBra (YM-8801) is a breast pump powered by lithium-ion battery, utilizing an embedded control program to manage all device functions. The user interface allows the user to switch from stimulation and expression modes and control the vacuum levels within those modes.

All available modes consist of 9 vacuum levels. The Motion InBra (YM-8801) is capable of providing vacuum levels from 80-160 mmHg with cycling rates from 100-120 cycles per minute in stimulation mode and vacuum levels from 80-280 mmHg with cycling rates from 35-75 cycles per minute in expression mode. The device is charged with a 5 V DC adaptor and powered by an internal rechargeable lithium-ion polymer battery. The motor unit operates on embedded software. Software updates by end-users are not supported. The subject device is for repeated use by a single user in a home environment. The device is provided non-sterile.

The motor unit operates on a rechargeable battery and does not function when charging. The rechargeable battery can be charged from the external USB adaptor if the motor unit is not in operation.

The Motion InBra Wearable Breast Pump includes 2-Phase Expression Technology: Stimulation and Expression Phases. The Stimulation Phase initiates with a rapid suction pattern designed to trigger the milk ejection reflex and promote milk flow. In contrast, the Expression Phase begins with a slower and deeper suction rhythm, optimized for effective milk extraction once let-down has occurred. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

The operating life of the Motion InBra Wearable Breast Pump is 150 hours. The expected operating life of the washable parts (milk container, breast shield, insert and membrane) is 3 months.

All other components (i.e., motor unit/housing) of the subject device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 175 and 21 CFR 177.

7. Indications for Use

The Motion InBra (YM-8801) wearable breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Motion InBra (YM-8801) 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 with the Predicate Device

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

Table 1: Comparator Table for Subject and Predicate Devices

	Motion InBra (YM-8801) wearable breast pump K253149 Subject Device	**Lucy Breast Pump K213311 Predicate Device**	**Comparison**
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Regulatory Class	Class II	Class II	Same
Patient Population	Lactating Women	Lactating Women	Same
Indications for Use	The Motion InBra (YM-8801) wearable breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Motion InBra (YM-8801) powered breast pump is intended for a single user. This breast pump is intended to be used in a home environment.	The Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast Pump is intended for a single user	Similar
Single/double pump	Single or double	Single or double	Same
Pump Type	Wearable	Wearable	Same

Media separation (backflow protection)	Yes	Yes	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Expression pattern	2-Phase	2-Phase	Same
Power supply	Li-Ion Battery	Li-Ion Battery	Same
Suction levels (Stimulation)	80-160 mmHg	75-280 mmHg	Different
Suction levels (Expression)	80-280 mmHg	75-280 mmHg	Different
Cycles per minute (Stimulation)	100 to 120 cpm	30 to 100 cpm	Different
Cycles per minute (Expression)	35 to 75 cpm	30 to 100 cpm	Different
Suction levels	9 Levels for expression, stimulation	4 Levels for expression and 3 for stimulation	Different
User Interface	On-Off/pause button, let down mode button, increase/decrease vacuum, LED display	On-Off button, mode selection, vacuum adjustment, LED display	Similar
Materials	Polypropylene breast shield in size 24 mm provided within the configuration. Silicone Inserts (15mm / 18mm / 21mm) Motor unit housing: acrylonitrile-butadiene-styrene (ABS)	Circular Shape - Polypropylene flange	Different
Adjustable Suction Levels	Yes	Yes	Same
Mobile Application	No	No	Same
Design	Wearable pump with combined Milk Collector and Flange	Wearable pump with combined Milk Collector and Flange	Same

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

The subject and predicate devices have similar technological features, including user interface, wearable design, and power supply. However, as shown in the table above, there are technological differences between the subject and predicate device, including different vacuum specifications, materials, and available vacuum levels. 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 Performance Testing

Biocompatibility

The biocompatibility evaluation for the Motion InBra (YM-8801) wearable breast pump was conducted in accordance with the 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,"" as follows:

- Cytotoxicity (ISO 10993-5:2009)

- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-10:2021)

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety
Testing was conducted in accordance with the following standards:

- ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance),
- 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, 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 the FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices," issued June 6, 2022 and IEC 60601-1-2:2014 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
Other 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 tubing.
- 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 remains functional during its stated battery life.

10. Conclusion

The results of the performance testing described above demonstrate that the Motion InBra (YM-8801) wearable breast pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.