April 12, 2024

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

Re: K232608
Trade/Device Name: Duo Hands-Free Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 14, 2024
Received: March 15, 2024

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.

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)*
K232608

Device Name
Duo Hands-Free Breast Pump

Indications for Use *(Describe)*
The Duo Hands-free breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.

The Duo 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.

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510(k) Summary – K232608

1. Submitter Information

Applicant: Medela LLC.
Phone: (800) 435-8316
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: April 11, 2024

4. Device Information

Device Name:	Duo Hands-Free 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:	Solo/Swing Maxi breast pumps
510(k) Number:	K210759
Manufacturer:	Medela LLC

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

6. Device Description

The Duo Hands-Free breast pump is an electrically powered breast pump to be used in a home environment by a single user. The device is provided non-sterile and can be used on one breast (single pumping) or on both breasts at the same time (double pumping).

The device consists of the pump unit, two Hands-free Collection Cups (breast shields, membranes, outer shells), and tubing. The breast pump provides wireless connectivity via a Bluetooth Low Energy (BLE) 4.2 compliant protocol and is compatible with the Medela Family mobile application. The BLE component does not offer control of the breast pump and is only meant to store the information sent from the breast pump (such as session length, phases and vacuum intensity levels) and log additional information related to their pumping session. The device has four buttons allowing the user to power the device on/off, select between two pumping modes (expression, and stimulation), and control vacuum strength within each mode (9 levels of vacuum strength in each mode). The pump is powered by an internal, non-replaceable, rechargeable lithium-ion battery which is charged using the included AC power supply and cable. The subject device can be operated while plugged into AC power.

The Duo Hands-free breast pump utilizes a microcontroller executing embedded software to interpret user inputs and modulate the voltage applied to a DC motor and a solenoid to produce a negative vacuum pressure applied to the user. The vacuum is generated by turning on the motor, incrementally drawing air out of the pump set on each rotation and expelling it into the atmosphere. When the cycle is complete, the solenoid valve is opened, relieving the vacuum. Vacuum generated by the breast pump unit is applied to the membrane in the Hands-free Collection Cup pump set causing it to displace away from the breast and to apply vacuum to the breast. Vacuum applied to the breast will cause milk to be expressed and to accumulate on the milk valve. Once the vacuum is relieved by the solenoid valve, milk will fall through the milk valve into the outer shells, and the cycle is repeated.

All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Duo Hands-free Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Duo Hands-free Breast Pump is intended for a single user. The 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

	Duo Hands-Free Breast Pump K232608 Subject Device	**Solo/Swing Maxi breast pumps K210759 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 Duo Hands-free breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Duo Hands-free breast pump is intended for a single user. The breast pump is intended to be used in a home environment.	The Solo/Swing Maxi breast pumps are powered breast pumps to be used by lactating women to express and collect milk from their breasts. The Solo/Swing Maxi breast pumps are intended for a single user. The breast pumps are intended to be used in a home environment.	Same
Single/double pump	Single or double	Single or double	Same
Media separation (backflow protection)	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Expression pattern	2-Phase	2-Phase	Same

Power supply	Li-Ion Battery or mains	Li-Ion Battery or mains	Same
Suction levels (expression)	-45 to -140 mmHg	-45 to -140 mmHg	Same
Suction levels (stimulation)	-45 to -245 mmHg	-45 to -245 mmHg	Same
Cycles per minute (expression)	Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level)	Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level)	Same
Cycles per minute (stimulation)	111 cpm	111 cpm	Same
Suction levels	9 expression, 9 stimulation	9 expression, 9 stimulation	Same
User Interface	4-button interface: On-off/pause , let-down, increase vacuum, decrease vacuum	4-button interface: On-off/pause , let-down, increase vacuum, decrease vacuum	Same
Adjustable Suction Levels	Yes	Yes	Same
Mobile Application	Yes	Yes	Same
Design	Mobile/Portable for use in-bra	Mobile/Portable	**Different**
Accessories	Breast Shields, Membranes Outer shells (5 oz), Tubing, USB power adaptor with cable	Breast shields Connectors (membrane and connector body) Bottles (5 oz) Bottle stands Tubing USB power adaptor with cable	**Different**

The indications for use of the subject and predicate device are identical, and 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, mobile application, power supply, and suction levels/cycle speeds. However, as shown in the table above, there are some technological differences between the subject and predicate device, including different overall design and included accessories. 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

Biocompatibility information was provided in accordance with Attachment G of 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."*

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 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 Edition 2.1 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 in accordance with IEC 60601-1-2 Edition 4.1 2020-09 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."*

Cybersecurity
Cybersecurity information was documented in accordance with recommendations in the 2023 FDA Guidance document, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."*

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 device meets 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 Duo Hands-Free Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.