August 11, 2021

Medela LLC
℅ Jenni Vescovo
Team Leader Global Regulatory Affairs
Medela AG
Lättichstrasse 4b
Baar, Zug 6340
Switzerland

Re: K210759
Trade/Device Name: Solo™, Swing Maxi™
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 9, 2021
Received: July 12, 2021

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210759

Device Name
Solo™
Swing Maxi™

Indications for Use *(Describe)*
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.

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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5.1 510(k) Summary Information

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

Date Summary Prepared:	August 10, 2021
Submitter/Applicant:	Medela LLC 1101 Corporate Drive McHenry, IL 60050 Phone: 815-578-2200 Fax: 815-759-2548
Primary Contact Person:	Jenni Vescovo Medela AG Team Leader, Global Regulatory Affairs Phone: +41 41 562 1328 Email: Jenni.Vescovo@medela.com
Device Information	Trade/Device Name: Solo™ / Swing Maxi™ Regulation Name: Powered Breast Pump Regulation Number: 21 CFR§884.5160 Product Code: HGX (Pump, Breast, Powered) Regulatory Class: II
Predicate Device Information	K191653 Manufacturer: Medela AG Device Name: Freestyle Flex™ The predicate device has not been subject to a design-related recall.

5.2 Device Description

Solo™ and Swing Maxi™ are breast pump systems intended to be used in a home environment (or similar such as an office). Solo™ and Swing Maxi™ comprise a pump unit, power adapter, and one (Solo™) or two (Swing Maxi™) PersonalFit Flex™ connectors that include the connector body, membrane (diaphragm), and connector back cap. The breast pump systems also include breast shields (21, 24, 27, and 30 mm), bottle, bottle lid, bottle stand, and tubing. The device is provided non-sterile.

The breast pumps can be used on one breast (single pumping; Solo™ and Swing Maxi™)) or on both breasts (double pumping) at the same time (Swing Maxi™).

The Solo™ and Swing Maxi™ breast pumps feature 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. A DC motor is used to drive a membrane aggregate. This membrane aggregate creates the negative pressure (suction) required to extract the breast milk. The pump unit includes the following features:

- user-adjustable controls: "On/Pause/Off" for powering on/off or pausing the device, "Let-down" for switching between pumping modes, and "Increase vacuum"/ "Decrease vacuum" for controlling vacuum intensity levels;
- a port for connection of the tubing that channels the vacuum for breast pumping;
- a port for connection of the power supply;
- a central LED light as status indicator; and
- a textile lanyard as an interface to the user's clothes/body.

The Solo™ and Swing Maxi™ breast pump systems allow the user to adjust the vacuum levels in both phases (stimulation and expression). The powered breast pumps are preprogrammed with variable vacuum levels and cycle rates. The powered breast pumps are capable of providing vacuum levels from -45 to -140 mmHg with cycle speeds up to 111 cycles per minute for stimulation and from -45 to -245 mmHg with cycle speeds from 75 to 45 cycles per minute for expression.

Two different product configurations are available for the Swing Maxi™ breast pump: without and with Bluetooth®. These two product configurations share the same mechanical and electrical design components; however, the Swing Maxi™ breast pump with Bluetooth® additionally features always-on enabled Bluetooth® connectivity. This allows monodirectional wireless data transmission from the breast pump to a Bluetooth®-enabled personal mobile device, such as a smartphone or tablet computer. When the Medela Family™ smart application is installed on a compatible mobile device and the device is paired via Bluetooth® with the breast pump unit, the user can: automatically record pumping data (session length, phases, and vacuum intensity levels), manually input the amount of milk expressed, and get notified when the battery is low as indicated in provided instructional material and in-app information.

5.3 Indications for Use

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.

5.4 Comparison of Technological Characteristics

The Solo™ / Swing Maxi™ breast pumps have similar indications for use, intended use, and has similar fundamental technology as the legally marketed predicate device to which substantial equivalency is claimed, the Freestyle Flex™ breast pump (K191653). In addition, several Medela breast pumps are referenced to demonstrate further substantial equivalence to prior devices.

1. Medela Pump In Style® breast pump (K200508) as it includes the same connectors as the subject device.

2. Medela Pump In Style® Advanced breast pump (K181937) as it includes the same breast shields as the subject device.

3. Medela Symphony® (K020518, K151632) as it is the original Medela device with the same 2-Phase Expression® Technology (Stimulation and Expression) as the subject device.

Characteristic	Freestyle Flex™ (Predicate Version) - K191653	Solo™ (Subject Device) – K210759	Swing Maxi™ (Subject Device) – K210759	
			Without Bluetooth®	With Bluetooth®
Indications for Use	The Freestyle Flex™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle Flex™ 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.		
Single User Device	Yes	Yes	Yes	
Environment of Use	Home	Home	Home	
Sterility	Not sterile	Not sterile	Not sterile	
User Control/ Interface	• DC input terminal/power port • 5-button interface: On/Off, Let-down, Increase vacuum, Decrease vacuum, Start/Pause • Integral tubing ports for single or double pumping	• DC input terminal/ power port • 4-button interface: On/Pause/Off, Let-down, Increase vacuum, Decrease vacuum • Integral tubing port for single pumping	• DC input terminal/ power port • 4-button interface: On/Pause/Off, Let-down, Increase vacuum, Decrease vacuum • Integral tubing port for double or single pumping	
Visual Indicator	LED display	LED light (status indicator)	LED light (status indicator)	
Pumping Options	Single or double pumping	Single pumping	Single or double pumping	

Medela LLC
Solo™ / Swing Maxi™ Breast Pump
Traditional 510(k)

Characteristic	Freestyle Flex™ (Predicate Version) - K191653	Solo™ (Subject Device) – K210759	Swing Maxi™ (Subject Device) – K210759	
			Without Bluetooth®	With Bluetooth®
Adjustable Suction Levels	Yes	Yes	Yes	
Breast Shields	PersonalFit Flex™ breast shields (21, 24, 27, 30 mm) featuring 360º rotatable oval-shape, soft rim, and 105º opening angle PersonalFit Flex™	PersonalFit Flex™ breast shields (21, 24, 27, 30 mm) featuring 360º rotatable oval-shape, soft rim, and 105º opening angle	PersonalFit Flex™ breast shields (21, 24, 27, 30 mm) featuring 360º rotatable oval-shape, soft rim, and 105º opening angle	
Replaceable/ Detachable Components of the Breast Pump	• Connector sets (connector body and membrane) • Bottles 5 oz (150 ml) with lids • Bottle stands • Freestyle Flex™ Tubing • Carry bag • Cooler with cooling element • USB power adaptor with cable • Nursing pads (sample)	• Connectors (membrane and connector body) • Bottles 5 oz (150 ml) with lids • Bottle stands • Tube assembly Solo • USB power adaptor with cable	• Connectors (membrane and connector body) • Bottles 5 oz (150 ml) with lids • Bottle stands • Tube assembly Swing Maxi/ Freestyle Flex • USB power adaptor with cable	
Cleaning Method	• Pump unit: wipe with clean towel, moistened with drinking-quality water • Breast shields, connectors, and membranes, bottles, and lids: hand wash in warm soapy water, rinse in drinking-quality water, air dry on a clean, unused; wash in dishwasher alternatively; sanitize in boiling water • Tubing: rinse tubing with drinking-quality water, wash in warm soapy water, rinse with clear water, shake out and hang to air dry	• Pump unit: wipe with clean, damp towel. • Breast shields, connectors, and membranes, bottles, and lids: wash and sanitize. • Tubing: Rinse tubing by pouring cool water into both short tubing ends until it flows out of the long tubing end. Wash the tubing in warm, soapy water and rinse tubing with clear water. Shake out water droplets and hang to air dry.	• Pump unit: wipe with clean, damp towel. • Breast shields, connectors, and membranes, bottles, and lids: wash and sanitize. • Tubing: Rinse tubing by pouring cool water into both short tubing ends until it flows out of the long tubing end. Wash the tubing in warm, soapy water and rinse tubing with clear water. Shake out water droplets and hang to air dry.	
AC/DC Power Source	• Input: 100-240 V AC, 50/60 Hz, 0.4 A max. • Output: 5 V DC, 2 A	• Input: 100-240 V AC, 50/60 Hz, 0.5 A max • Output: 5 V DC, 2 A	• Input: 100-240 V AC, 50/60 Hz, 0.5 A max • Output: 5 V DC, 2 A	

Characteristic	Freestyle Flex™ (Predicate Version) - K191653	Solo™ (Subject Device) – K210759	Swing Maxi™ (Subject Device) – K210759	
			Without Bluetooth®	With Bluetooth®
Battery Power Source	Rechargeable Li-Ion battery, 3.7 V DC – 2,750 mAh	Rechargeable Li-Ion battery, 3.6 V DC – 2,500 mAh	Rechargeable Li-Ion battery, 3.6 V DC – 2,500 mAh	
Software	Embedded	Embedded	Embedded	
Electronic Data Interface	Bluetooth® Low Energy (BLE, version 4.0+) certified module. The BLE module is used to broadcast pumping session data to the MyMedela application (on a compatible device). The pumping session data transmitted by the breast pump include pumping duration, pumping level, battery status. The breast pump cannot be controlled via the BLE interface.	-	-	Bluetooth® Low Energy (BLE, version 4.0+) certified module. The BLE module is used to broadcast pumping session data to the Medela Family™ application (on a compatible device). The pumping session data transmitted by the breast pump include pumping duration, pumping level, battery status. The breast pump cannot be controlled via the BLE interface.
2-phase expression	Yes	Yes	Yes	
Let-Down button	Yes	Yes	Yes	
Cycling Control Mechanism	Microcontroller	Microcontroller	Microcontroller	
Adjustable Suction Levels	Yes	Yes	Yes	
Suction Settings (Pumping Levels)	9	9	9	
Vacuum Range	• Stimulation: -45 to -140 mmHg • Expression: -45 to -245 mmHg	• Stimulation: -45 to -140 mmHg • Expression: -45 to -245 mmHg	• Stimulation: -45 to -140 mmHg • Expression: -45 to -245 mmHg	
Maximum Vacuum Expression	-270 mmHg	-270 mmHg	-270 mmHg	
Cycle Speed (cycle per minute)	• Stimulation: 111 • Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level)	• Stimulation: 111 • Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level)	• Stimulation: 111 • Expression: 75 (at lowest vacuum level) to 45 (at highest vacuum level)	

Characteristic	Freestyle Flex™ (Predicate Version) - K191653	Solo™ (Subject Device) – K210759	Swing Maxi™ (Subject Device) – K210759	
			Without Bluetooth®	With Bluetooth®
Backflow Protection	Yes - connector with silicone membrane prevents milk backflow into the tubing and pumping mechanism.	Yes - connector with silicone membrane prevents milk backflow into the tubing and pumping mechanism.	Yes - connector with silicone membrane prevents milk backflow into the tubing and pumping mechanism.	

The subject and predicate devices have identical indications for use and the same intended use – expressing milk from the breasts of lactating women. The subject and predicate device have similar technological features. The subject and predicate device differ in the battery specifications and provided accessories. These differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

5.5 Summary of Non-Clinical Tests

The Solo™ / Swing Maxi™ breast pumps comply with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following performance data are provided in support of the substantial equivalence determination:

- Electrical Safety testing in accordance with ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical Electrical Equipment - Part 1: General requirements for Basic Safety and Essential Performance.
- Electrical safety testing for use in home in accordance with IEC 60601-11:2015 (Edition 2.0), 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.
- Risk analysis in accordance with ISO 14971:2007 (Second Edition), Medical Devices - Application of Risk Management to Medical Devices.
- Electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014 (Edition 4.0), Medical electrical equipment - Part 1-2: General requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
- 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," dated September 04, 2020 and concluded that no new testing was required as all patient-contacting materials are identical to those used in the predicate device Freestyle Flex™ (K191653).
- The software validation as provided in accordance with the FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005. The software for the subject device was considered as a "Moderate" level of concern, since prior to mitigations of hazards, failure of the software could lead to minor injury, such as pain.
- Bench testing was conducted with settings to determine the minimum and maximum vacuum levels of the pumps as well as cycle rate compared to the specifications. The specifications were met under conditions of single pumping (for Solo™) and of single and double pumping (for Swing Maxi™) modes with power supply from both the internal battery and external AC/DC power adaptor.
- Battery and pump use life testing was conducted to demonstrate that the device maintains its specifications throughout its use life.

5.6 Conclusions

The subject and predicate devices have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate the subject device is substantially equivalent to the predicate device.