October 17, 2019

Medela AG
℅ Adrienne Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D. C. 20005

Re: K191653
Trade/Device Name: Freestyle Flex™
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 17, 2019
Received: September 17, 2019

Dear Adrienne Lenz:

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); 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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191653

Device Name
Freestyle Flex™

Indications for Use *(Describe)*
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.

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 – K191653

In accordance with 21 CFR § 807.92, the following summary of information is provided:

DATE: October 17, 2019

SUBMITTER

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DEVICE

Trade/Device Name: Freestyle Flex™
Regulation Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Common Name: Powered Breast Pump
Product Code: HGX
Regulatory Class: II

PREDICATE DEVICE

K150499
Manufacturer: Medela AG

Device Name: Freestyle® Deluxe, Freestyle® Solution Set, Freestyle® Basic, Freestyle® Motor Warranty

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

REFERENCE DEVICES

Three additional Medela breast pumps are used as reference devices for the following rationales:

- Medela Sonata breast pump (K161725) as it includes the same Bluetooth communication to the MyMedela Application for mobile devices as the subject device.
- Medela Pump In Style® Advanced breast pump (K181937) as it includes the same PersonalFit Flex breast shields as the subject device.
- Medela Symphony breast pump (K020518, K151632) as it is the original Medela device studied with the same two-phase expression system as the subject device.

DEVICE DESCRIPTION:

The Medela Freestyle Flex™ breast pump system is comprised of the Freestyle Flex™ pump (motor unit), the PersonalFit Flex connector (including membranes and connector bodies), PersonalFit Flex breast shields (21, 24, 27, 30 mm), tubing, bottles, carry bag, cooler with cooling element, and Power Adapter.

The Medela Freestyle Flex™ breast pump system is used to express and collect milk from the breast of a lactating woman. The system is intended for daily use in a home (or similar environment such as an office) to supplement breastfeeding by a single user. Pumping with the Freestyle Flex™ breast pump can be performed on one breast (single pumping) or on both breasts at the same time (double pumping).

The Freestyle Flex™ breast pump allows the user to adjust the vacuum levels. Two suction patterns are pre-programmed with variable vacuum levels and cycle rates (pump speed). The powered breast pump is capable of providing vacuum levels from -45 to -245 mmHg with cycle rates up to 111 cycles per minute. The device is AC/DC powered and incorporates a DC motor with membrane aggregate in its pump motor unit. The device is provided non-sterile.

The Freestyle Flex™ breast pump provides the following user features:

- Five buttons for user adjustment of on/off, let-down, increase vacuum, decrease vacuum, start/pause.
- 2-Phase Expression® Technology designed to mimic a baby's natural nursing rhythm:
    - Stimulation Phase (phase 1): Suction pattern with fast cycles and low vacuum to start milk flowing.

  - Expression Phase (phase 2): Suction pattern with slower cycles and higher vacuum to express more milk gently and efficiently.
- "Let-down" control to change between stimulation phase and expression phase.
- Option of either single or double breast pumping.

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.

SUBSTATIAL EQUIVALENCE DISCUSSION

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE COMPARED TO THE PREDICATE DEVICE

The table below identifies key similarities and differences between the subject device (Freestyle Flex™) breast pump and the legally marketed predicate device (K150499).

Table 1. Comparison of Freestyle Flex™ to Predicate Device

	Freestyle® Breast Pump (Predicate Device) K150499	**Freestyle Flex™ Breast Pump (Subject Device) K191653**
General Device Characteristics		
Indications for Use	The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts. The Freestyle® is intended for a single user.	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.
Single user device	Yes	Yes
Environment of Use	Home	Home
Regulation Number ***Product Code*** ***Device Class***	21 CFR 884.5160 HGX II	21 CFR 884.5160 HGX II
Sterility	Not sterile	Not sterile

	Freestyle® Breast Pump (Predicate Device) K150499	**Freestyle Flex™ Breast Pump (Subject Device) K191653**
User Interface and Controls		
User Control	On/off switch, let-down button, vacuum/cycle adjustment controls, memory	5-button interface: on/off, let-down, increase vacuum, decrease vacuum, start/pause
Visual Indicator	LCD display	LED display
Pumping Options	Single or Double	Single or Double
Accessories	• Media separation • Media separation barrier • Bottle collars • Bottle discs • Bottles (5 oz) with lids • PersonalFit™ breast shields (21, 24, 27, 30, 36 mm) • Bottle holders • AC adapter • Vehicle adapter • Battery • Tubing • Tote bag • Cooler bag • Ice pack • Milk Storage Bags • Nursing pads • Lanolin • Breastfeeding resource guide, log and storage magnet • Cleaning soap • Microsteam bags • Easy expression bustier • Feeding nipples	• Freestyle Flex™ Connector sets (connector body and membrane) • Bottles (5 oz) with lids • PersonalFit™ Flex breast shields (21, 24, 27, 30 mm) • Bottle stands • Freestyle Flex™ Tubing • Carry bag • Cooler with cooling element • USB charger • Nursing pads (sample)

	Freestyle® Breast Pump (Predicate Device) K150499	**Freestyle Flex™ Breast Pump (Subject Device) K191653**
Cleaning	• Tubing – wash or sanitize weekly, or if milk or condensation is present in the tubing • Breast pump kit and bottles – wash and sanitize • Breast pump carrying case/bag – wipe with clean, damp cloth	• Motor unit – wipe with clean towel moistened with drinking-quality water • Breast shield, connectors and membranes, bottles and lids – hand wash in warm soapy water, rinse in drinking-quality water, air dry on a clean, unused towel; 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
Specifications		
Power Supply	• Li-Ion battery • AC adaptor provided	• Li-ion battery (3.7 V, 2,750 mAh) • AC power adapter (Input: 100-240V, 50-60Hz, max. 0.4A; Output: 5 V DC, 2 A) • Electrical protection (Class II)
Adjustable Suction Levels	Yes	Yes
Suction Settings (Pump Levels)	9	9
Suction Levels (stimulation)	-40 to -140 mmHg	-45 to -140 mmHg
Cycles per Second (stimulation)	1.7-1.93	1.85
Suction Levels (expression)	45 – 245 mmHg	45 – 245 mmHg
Cycles per Second (Expression)	0.83-1.36	0.75-1.25
Maximum vacuum	-270 mmHg	-270 mmHg
Let-Down Button	Yes	Yes
Back Flow Protection	Yes – connector with membrane provide media separation to protect against backflow.	Yes – connector with membrane provide media separation to protect against backflow.
Software	Embedded	Embedded

	Freestyle® Breast Pump (Predicate Device) K150499	**Freestyle Flex™ Breast Pump (Subject Device) K191653**
Cycling Control Mechanism	Microcontroller	Microcontroller
2-phase expression	Yes	Yes
Electronic Data Interface	N/A	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.

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 different technological features. The subject and predicate devices operate at different cycle values for stimulation and expression modes. The user interface varies between the subject, LED indicators, and predicate, LCD screen. The subject device also includes Bluetooth connectivity to transmit data to a mobile app. These differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

SUMMARY OF NON-CLINICAL TESTS

The Freestyle Flex™ breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment, and usability. The following non-clinical performance data were provided in support of the substantial equivalence determination:

- Biocompatibility evaluation was completed according to the FDA guidance "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," dated June 16, 2016, and concluded that no new testing was required as all patient-contacting materials are identical to those used in cleared Medela breast pumps (K181937).

- Testing in accordance with the following standards:
  - AAMI / ANSI ES60601-1:2005/A1:2012, Medical Electrical Equipment: Part 1: General Requirements for Basic Safety and Essential Performance
  - IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
  - 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
  - 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
  - ISO 10079-1: 2015 Medical Suction Equipment - Part 1: Electrically Powered Suction Equipment

- Risk analysis in accordance with ISO 14971:2007

- Software Validation: The software/firmware verification and validation were 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.

- Bench performance testing was conducted with internal test protocols to determine the minimum and maximum vacuum levels of the pump, as well as cycle rate compared to its specifications. The specifications were met for vacuum levels and cycle rate, for single and double pumping with all breast shield sizes and both battery and AC power. Battery and pump use life testing were conducted to demonstrate the device maintains its specifications throughout its use life under varying power sources (AC, battery).

CONCLUSION:

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.