June 15, 2020

Medela LLC
PJ Pasia
Manager, Regulatory Affairs
1101 Corporate Drive
McHenry, IL 60050

Re: K200508
Trade/Device Name: Pump In Style®
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 13, 2020
Received: May 14, 2020

Dear PJ Pasia:

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)*
K200508

Device Name
Pump In Style®

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K200508

In accordance with 21 CFR 807.92(a) the following summary of information is provided:

Date Summary Prepared:	June 10, 2020
Submitter/Applicant	Medela LLC 1101 Corporate Drive McHenry, IL 60050 Phone: 815-578-2200 Fax: 815-759-2548
Primary Contact Person:	PJ Pasia Medela LLC Manager, Regulatory Affairs Phone: 815-578-2455 Cell: 815-529-9613 Fax: 815-759-2563 Email pj.pasia@medela.com
Device Information	Trade/Device Name: Pump In Style® Regulation Name: Powered Breast Pump Regulation Number: 21 CFR 884.5160 Common Name: Powered Breast Pump Product Code: HGX Product Code Name: Pump, Breast, Powered Regulatory Class: II Review Panel: Obstetrics/Gynecology
Predicate Device Information	K181937 Manufacturer: Medela LLC Device Name: Pump In Style® Advanced The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:
The Pump In Style® breast pump is used to express and collect milk from the breast of a lactating woman. The device is intended for daily use in a home environment to supplement breastfeeding by a single user. Pumping can be performed on one breast (single pumping) or both breasts at the same time (double pumping).

The Pump In Style® breast pump is comprised of the breast pump unit, connector (including membranes, connector body and cap), breast shields, tubing, collection bottles, and power adaptor. In addition, optional accessories such as carry bag, bottle stand, battery pack, cooler bag, cooling element, vehicle power adaptor and additional milk collection containers may be included in the packaging as part of the product offering.

The Pump In Style® breast pump has user-adjustable controls for powering the device on/off, switching between two pumping modes, stimulation and expression, and controlling vacuum level within each of the modes. The Pump In Style® breast pump is capable of providing vacuum levels from -50 to -240 mmHg with cycle rates up to 140 cycles per minute. The tubing port is for connection of the tubing for pumping. The power supply port is for connection of the power supply or portable vehicle adaptor or battery pack.

The Pump In Style® breast pump provides the following user features:

- 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.
- The option of either single or double breast pumping.

INDICATIONS FOR USE:
Pump In Style® is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This powered breast pump is intended for a single user and is intended to be used in a home environment.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

The Pump In Style® has the same intended use and has similar fundamental technology as the legally marketed predicate device to which substantial equivalency is claimed, the Pump In Style® Advanced breast pump (K181937). The following table compares the subject device to the predicate with respect to the indications for use and technological characteristics:

Characteristic	Pump In Style® Advanced (Predicate Device) – K181937	Pump In Style® (Subject Device) – K200508
Indications for Use	The Pump In Style® Advance breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The pump is intended for a single user.	Pump In Style® is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This powered breast pump is intended for a single user and is intended to be used in a home environment.
Contraindications	None	None
Environment of Use	Home	Home
Single user device	Yes	Yes
User Control/Interface	• DC input terminal/power port • On/Off rotary switch/Potentiometer to increase and decrease vacuum • Let-Down Button • Integral tubing ports for double or single pumping	• DC input terminal/ power port • On/Off Button • Let-Down Button • Increase vacuum button • Decrease vacuum button • Integral tubing port for double- or single- pumping
Visual Indicator	No visual indicator	No visual indicator
Pumping options	Single or double pumping	Single or double pumping
User Skin Contact	Breast shields	Breast shields
Adjustable Suction Levels	Yes	Yes
Breast Shields	Oval-shaped and round (Polypropylene and thermoplastic elastomer polypropylene) breast shields	Oval-shaped (Polypropylene and thermoplastic elastomer polypropylene) breast shields
Cleaning Method	Breast pump/case - wipe with clean, damp cloth Tubing - wash only if dirty or milk is present in the tubing. Breast pump set, bottles, lids—wash and sanitize	Breast pump - wipe with clean damp cloth and dry with a clean towel Tubing - clean only if condensation in tubing is present Tubing - if milk appears in tubing, user is instructed not to attempt to clean tubing, but to call Medela customer service. Breast pump set, bottles, lids—wash and sanitize
Replaceable/detachable components of the breast pump	Breast shield Connector Valve Membrane Tubing Power supply Faceplate	Breast shield Membrane Connector Body Connector Cap Tubing Power supply
Power Source- Direct plug-in	Switching Power Supply Input: 100-240 VAC, 50/60Hz, 0.7A. Output: 9VDC, 2A	Switching Power Supply Input: 100-240 VAC, 50/60Hz, 0.7A. Output: 9VDC, 2A
Power Source- External battery pack	AA batteries (Alkaline, Ni-MH)	AA batteries (Alkaline, Ni-MH)

Characteristic	Pump In Style® Advanced (Predicate Device) – K181937	Pump In Style® (Subject Device) – K200508
Power Source - Portable Vehicle Adapter	Type: Switching vehicle power adapter Input Rating: 12-24VDC Output Rating: 9VDC, 1.0A	Type: Switching vehicle power adapter Input Rating: 12-24VDC Output Rating: 9VDC, 1.0A
Software	Embedded	Embedded
Electrical Insulation Class	Class II (double insulated)	Class II (double insulated)
IP-Protection	IP-22	IP-22
Protection Type	BF	BF
Operating Conditions	Humidity: 15 to 93% RH Temperature: +5°C to +40°C Pressure: 70 to 106 kPa	Humidity: 15 to 93% RH Temperature: +5°C to +40°C Pressure: 70 to 106 kPa
Storage and Transport Conditions	Humidity: 15 to 93% RH Temperature: -25°C to +70°C Pressure: 70 to 106 kPa	Humidity: 15 to 93% RH Temperature: -25°C to +70°C Pressure: 70 to 106 kPa
Dimensions (HxWxD)	165 mm x 165 mm x 135 mm	144 mm x 77 mm x 111 mm
Housing Material	Metal	Upper Housing: Makrolon 2607 Polycarbonate Lower Housing: Makrolon 2607 Polycarbonate Foot: Versaflex (TPE) Thermoplastic Elastomer Keypad: Silicone LIM 6050 Tubing Port: Polypropylene
Fabric Branding Loop	N/A	Polyester, 100% Virgin
Vacuum aggregate type	Diaphragm-type assembly	Accumulator
Cycling Control Mechanism	Microcontroller	Microcontroller
Maximum vacuum - expression (double and single pumping)	-295 mmHg	-295 mmHg
Vacuum range – double pumping	-50 to -240 mmHg	-50 to -240 mmHg
Vacuum range – single pumping	-50 to -240 mmHg	-50 to -240 mmHg
Cycle Speed	97 to 140 cycles/minute (stimulation) 20 to 88 cycles/minute (expression)	97 to 140 cycles/minute (stimulation) 20 to 88 cycles/minute (expression)
Overflow protection	Yes- Diaphragm (integrated into the breast pump) prevents overflow of milk into the pumping mechanism.	Yes- connector with silicone membrane prevents milk overflow into the tubing and pumping mechanism.

SUMMARY OF NON-CLINICAL TESTS

The Pump In Style® breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home environment and usability. The following 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 within a risk management process" and concluded that no new testing was required, as the patient-contacting components are identical to those used in other cleared Medela breast pumps.
- Electrical Safety testing in accordance with AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. Medical Electrical Equipment: Part 1: General Requirements.
- Electrical safety testing for use in home in accordance with IEC 60601-11:2015, 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
- Electromagnetic compatibility testing in accordance with 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.
- Software/firmware verification and validation 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 this device is considered as a "minor" level of concern, since prior to mitigations of hazards, failures of the software are unlikely to cause any injury.
- Bench testing was conducted with settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications. The specifications were met for vacuum levels, cycle rate and backflow protection. These results held under conditions of single and double pumping modes with varying power sources (e.g. AC/DC power adaptor, portable vehicle adaptor, external battery pack).

CONCLUSION:

The comparison and analysis above demonstrate that the Pump In Style® breast pump is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.