



October 16, 2018

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

Re: K181937  
Trade/Device Name: Pump In Style® Advanced  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: July 17, 2018  
Received: July 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Sharon M. Andrews -**  
**S**

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K181937

Device Name

Pump In Style® Advanced

Indications for Use (Describe)

The Pump In Style® Advanced breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The powered breast pump is intended for a single user.

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

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

Date Summary Prepared: October 15, 2018

Submitter/Applicant Medela LLC  
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Device Information Trade/Device Name: Pump In Style® Advanced  
Regulation Name: Powered Breast Pump  
Regulation Number: 21 CFR§ 884.5160  
Common Name: Powered Breast Pump  
Device Classification Name: Pump, Breast, Powered  
Product Code: HGX  
Regulatory Class: II

Predicate Device Information K031614  
Manufacturer: Medela  
Device Name: Pump In Style® Advanced

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

**Device Description:**

The Pump In Style® Advanced breast pump and kit are 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 Pump In Style® Advanced breast pump can be performed on one breast (single pumping) or on both breasts at the same time (double pumping).

The Pump In Style® Advanced breast pump employs a control knob (potentiometer) for the user to adjust the vacuum levels. Two suction rhythms are pre-programmed with variable vacuum levels and cycle rates (pump speed). The powered breast pump is capable of providing vacuum levels from -50 to -240 mmHg with cycle rates up to 120 cycles per minute.

The device employs a gear-driven diaphragm-type vacuum pump, powered by a DC motor supervised by a microcontroller. The microcontroller drives the “H” bridge providing speed and directional control over the DC motor. The device is electrically powered from external batteries (AA batteries) or from an external direct plug-in AC power supply or from a vehicle lighter adapter. The device is provided non-sterile.

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

- Rotary knob for user adjustment of vacuum level/cycles and on/off
- 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 Pump In Style® Advanced breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The powered breast pump is intended for a single user.

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

### Determination of Substantial Equivalence:

The table below identifies key similarities and differences of the proposed Pump In Style® Advanced breast pump to the legally marketed predicate version of this device (K031614).

Table 5.1 Comparison of Pump In Style® Advanced to Predicate Device

|                                       | <b>Pump In Style® Advanced<br/>(Predicate Version)<br/>K031614</b>                                                                                                                                                                                                                                                                 | <b>Pump In Style® Advanced<br/>(Current Version)</b> |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| <b>General Device Characteristics</b> |                                                                                                                                                                                                                                                                                                                                    |                                                      |
| <b>Indications for Use</b>            | Powered breast pump to be used by lactating women to express and collect milk from their breasts. The powered breast pump is intended for a single user.                                                                                                                                                                           | Same                                                 |
| <b>Environment of Use</b>             | Home                                                                                                                                                                                                                                                                                                                               | Same                                                 |
| <b>Manufacturer</b>                   | Medela LLC                                                                                                                                                                                                                                                                                                                         | Same                                                 |
| <b>Regulation No.</b>                 | 21 CFR 884.5160                                                                                                                                                                                                                                                                                                                    | Same                                                 |
| <b>Device Class</b>                   | Class II                                                                                                                                                                                                                                                                                                                           | Same                                                 |
| <b>Suction Modes</b>                  | Stimulation and Expression                                                                                                                                                                                                                                                                                                         | Same                                                 |
| <b>Overflow protection</b>            | Membrane/Valve combination                                                                                                                                                                                                                                                                                                         | Same                                                 |
| <b>User Interface and Controls</b>    |                                                                                                                                                                                                                                                                                                                                    |                                                      |
| <b>User Control</b>                   | <ul style="list-style-type: none"> <li>On/Off rotary switch (potentiometer) to adjust vacuum levels</li> <li>“Let-Down” button (membrane switch), used to select between stimulation phase and expression phase.</li> <li>Integral tubing port for double or single pumping</li> <li>DC Input port for power connection</li> </ul> | Same                                                 |
| <b>Visual Indicator</b>               | No visual indicator                                                                                                                                                                                                                                                                                                                | Same                                                 |
| <b>Pumping options</b>                | Single and double pumping                                                                                                                                                                                                                                                                                                          | Same                                                 |

|                                                                 | <b>Pump In Style® Advanced<br/>(Predicate Version)<br/>K031614</b>                                                                                                                                                                                                          | <b>Pump In Style® Advanced<br/>(Current Version)</b>                                                                                 |
|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| <b>Adjustable Suction Level</b>                                 | Yes                                                                                                                                                                                                                                                                         | Same                                                                                                                                 |
| <b>User Skin Contact</b>                                        | Breast shield                                                                                                                                                                                                                                                               | Same                                                                                                                                 |
| <b>Cleaning Method</b>                                          | <ul style="list-style-type: none"> <li>• Tubing - wash or sanitize weekly, or if milk or condensation is present in the tubing</li> <li>• Breast pump kit and bottles – wash and sanitize</li> <li>• Breast pump carrying case/bag - wipe with clean, damp cloth</li> </ul> | Same                                                                                                                                 |
| <b>Specifications</b>                                           |                                                                                                                                                                                                                                                                             |                                                                                                                                      |
| <b>Power Source - AC Adapter</b>                                | Type: Linear Power Supply<br>Input Rating: 110- 120V, 60Hz, 18W<br>Output Rating: 9Vdc, 1.0A<br>Class 2 (double insulated)                                                                                                                                                  | Type: Switching Power Supply<br>Input Rating:<br>100-240V, 50-60Hz, 0.7A<br>Output Rating:<br>9Vdc, 2A<br>Class 2 (double Insulated) |
| <b>Software</b>                                                 | Embedded                                                                                                                                                                                                                                                                    | Same                                                                                                                                 |
| <b>Power Source-External Battery</b>                            | Type: AA batteries<br>Qty: 8 pcs.                                                                                                                                                                                                                                           | Same                                                                                                                                 |
| <b>Power Source- vehicle lighter adapter</b>                    | Type: Switching vehicle power adapter<br>Input Rating: 12-24Vdc<br>Output Rating: 9Vdc, 1.0A                                                                                                                                                                                | Same                                                                                                                                 |
| <b>Vacuum aggregate type</b>                                    | Diaphragm-type                                                                                                                                                                                                                                                              | Same                                                                                                                                 |
| <b>Cycling Control Mechanism</b>                                | Microcontroller                                                                                                                                                                                                                                                             | Same                                                                                                                                 |
| <b>Max Vacuum (mmHg)- Expression- double and single pumping</b> | Approx. -295 mmHg                                                                                                                                                                                                                                                           | Same                                                                                                                                 |
| <b>Vacuum range – double mmHg/kPa</b>                           | -50 to -240mmHg                                                                                                                                                                                                                                                             | Same                                                                                                                                 |
| <b>Vacuum range – single mmHg/kPa</b>                           | -50 to -240mmHg                                                                                                                                                                                                                                                             | Same                                                                                                                                 |
| <b>Cycle Speed</b>                                              | 120 Cycles                                                                                                                                                                                                                                                                  | Same                                                                                                                                 |
| <b>Breast Shields</b>                                           | Round only (Polypropylene)                                                                                                                                                                                                                                                  | Oval and round (Polypropylene and thermoplastic elastomer polypropylene)                                                             |

The subject and predicate devices have identical indications for use and the same intended use – expressing milk from the breasts of lactating women. Although the current version of the Pump In Style® Advanced has the same fundamental technology and principles of operation as the previously cleared version, several modifications have been made to the subject device. The subject and predicate devices do not have identical technological characteristics because the current version utilizes a switching AC power supply (Input: 100-240, 50/60Hz, 0.7A; Output: 9VDC, 2A) rather than a linear power supply of the predicate device (Input: 110-120 VAC, 60Hz 18W; Output: 9Vdc, 1.0A). In addition, the subject device includes oval shaped breast shields which are manufactured with a different material compared to the round breast shields of the

predicate device. These differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

### **SUMMARY OF NON-CLINICAL TESTS:**

The Pump In Style® Advanced breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following performance data were provided in support of the substantial equivalence determination:

- Biocompatibility evaluation in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
  - Cytotoxicity testing per ISO 10993-5:2009
  - Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
  - Irritation testing per ISO 10993-10:2010
- Electrical Safety testing in accordance with:
  - AAMI / ANSI ES60601-1:2005/A1:2012, Medical Electrical Equipment: Part 1: General Requirements.
  - Electrical safety testing for use in home in accordance with IEC 60601-1-11:2015, 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 Validation: The software/firmware verification and validation was 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 and overflow protection, as compared to its specifications. The specifications were met for vacuum levels, cycle rate and overflow protection. Battery use life testing was also conducted to demonstrate the subject device maintains its specifications throughout its use life. These results held under conditions of single and double pumping modes with varying power sources (e.g. AC/DC power, vehicle lighter adapter, external battery pack).

### **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.