



Food and Drug Administration  
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October 28, 2016

Medela, Inc.  
% Adrienne Lenz  
Member  
Pathway Regulatory Consulting, LLC  
W324S3649 County Road E  
Dousman, Wisconsin 53118

Re: K161725  
Trade/Device Name: Sonata™ breast pump and accessories  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered breast pump  
Regulatory Class: Class II  
Product Code: HGX  
Dated: September 23, 2016  
Received: September 27, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

For Division

Sincerely,

**Douglas Silverstein -S**

**2016.10.28 08:35:06 -04'00'**

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)

K161725

Device Name

Sonata™ breast pump and accessories

Indications for Use (Describe)

The Sonata breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Sonata 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

**K161725**

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

DATE: October 26, 2016

**SUBMITTER:**

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Medela Inc.  
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**PRIMARY CONTACT PERSON:**

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Phone: (262) 290-0023

**SECONDARY CONTACT PERSON:**

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Robert Sokolowski  
Director, Quality Assurance  
Medela Inc.

**DEVICE:**

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TRADE NAME: Sonata™ breast pump and accessories

Models: 58200 Sonata™ Breastpump Deluxe, 68053 Double Pumping Kit, retail, 68054 Connector spare parts kit, 68055 Silicone Membrane, retail, includes 2 silicone membranes, 68050 Power Adaptor, retail, 68052 Carry Bag, retail, 58105 Sonata™ Warranty Breast pump

COMMON/USUAL NAME: Powered Breast Pump

REGULATORY CLASS: Class II

CLASSIFICATION NAME: 21 CFR 884.5160 (Powered breast pump)

PRODUCT CODE: HGX (Pump, Breast, Powered)

PREDICATE DEVICE:

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K151632; Medela Symphony Breast Pump. The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:

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The Sonata™ 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. The system is not designed for mobile use. Pumping with the Sonata™ breast pump can be performed on one breast (single pumping) or on both breasts at the same time (double pumping).

Two suction rhythms are pre-programmed with variable vacuum levels and cycle rates (pump speed). The Sonata™ breast pump is capable of providing vacuum levels from -50 to -240 mmHg with cycle rates up to 120 cycles per minute.

The Sonata™ breast pump provides the following user features:

- Gear-driven vacuum pump design (linear piston), for quiet operation.
- LCD display, for user assistance/device status.
- Capacitive touch controls for user adjustment of vacuum level/cycles, phase selection “Let-down”, pattern selection, and audio chimes.
- 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.
- Protective membrane, designed to isolate the pump mechanism from the breast milk collection apparatus (prevent milk overflow into the pump). No vacuum can be created if the protective membrane is missing or damaged.
- User-friendly pump exterior, designed for ease of cleaning.

For a full list of device specifications, please see the Table 1. Comparison of Sonata to Predicate Device.

**INDICATIONS FOR USE:**

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The Sonata™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Sonata breast pump is intended for a single user.

**DETERMINATION OF SUBSTANTIAL EQUIVALENCE:**

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

The indications for use of Medela’s Sonata™ breast pump are the same as the predicate devices with the additional statement that it is intended for a single user. The subject and predicate device have the same intended use – to express and collect milk from the breast.

Sonata™ and the predicate device generate vacuum in a similar manner. A microprocessor-controlled DC motor provides motive force to a drive train which in turn moves a linear element to create volumetric expansion and vacuum.

The table below identifies key similarities and differences of the proposed Sonata breast pump to the legally marketed predicate device, the Symphony breast pump (K151632).

TABLE 1. COMPARISON OF SONATA TO PREDICATE DEVICE

	<b>Sonata™ (Subject Device), K161725</b>	<b>Symphony™ (Predicate Device), K151632</b>
<b><i>Indications for Use</i></b>	The Sonata™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Sonata™ breast pump is intended for a single user.	The Symphony™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.
<b><i>Environment of Use</i></b>	Home	Hospital, Home

	<b>Sonata™ (Subject Device), K161725</b>	<b>Symphony™ (Predicate Device), K151632</b>
<b><i>User Interface</i></b>	Hardware interfaces	Hardware interfaces
<b><i>User Control</i></b>	<p>State-dependent controls:</p> <p>Power Button (physical Switch)</p> <p>Capacitive touch switches for:</p> <ul style="list-style-type: none"> <li>• One Touch Let-Down</li> <li>• Silence Control</li> <li>• Start/Stop /Pause</li> <li>• Timer</li> <li>• Rhythm (Pattern) Selection</li> <li>• “Plus” increment value button used to adjust vacuum and timer settings</li> <li>• “Minus” decrement value button used to adjust vacuum and timer settings</li> </ul>	<p>State-dependent controls:</p> <p>On-Off membrane switch</p> <p>Let-Down Button (membrane switch), also used to select the Preemie+ initiation program</p> <p>Value-adjustment rotary control: Vacuum/Cycle-adjustment control</p>
<b><i>Visual Indicator</i></b>	<p>Liquid-crystal display (LCD)</p> <p>Light Emitting Diodes (LED) surrounding start/stop button: white at power up, green when pumping, flashing green when paused.</p>	Liquid-crystal display
<b><i>Audible Indicator</i></b>	<p>Internal Speaker (not alarm).</p> <p>Notification Chimes:</p> <ul style="list-style-type: none"> <li>• Button press</li> <li>• Button bookend (end of range reached)</li> <li>• Leak chime</li> <li>• Leak resolved chime</li> <li>• Timer chime</li> <li>• Letdown chime</li> </ul>	None
<b><i>Single/Double Pumping</i></b>	Single and double pumping	Single and double pumping

	<b>Sonata™ (Subject Device), K161725</b>	<b>Symphony™ (Predicate Device), K151632</b>
<b>Accessories</b>	<ul style="list-style-type: none"> <li>• Breast shield</li> <li>• Breast shield connector</li> <li>• Valve</li> <li>• Membrane</li> <li>• Tubing</li> <li>• Pump and Save Bags</li> <li>• Power Supply</li> <li>• Cooler</li> <li>• Carry bag</li> <li>• Closures/lids (for bottles)</li> <li>• Collection Containers</li> </ul>	<ul style="list-style-type: none"> <li>• Breast shield</li> <li>• Breast shield inserts</li> <li>• Valve</li> <li>• Membrane</li> <li>• Tubing</li> <li>• Bottles, with disks lids and caps</li> <li>• Trolley</li> <li>• Vehicle adapter</li> <li>• Power cord</li> <li>• Container Stand</li> <li>• Cooler</li> <li>• Colostrum and Collection Containers</li> <li>• Pump and Save Bags</li> </ul>
<b>Cleaning</b>	<ul style="list-style-type: none"> <li>• Breastpump/case - wipe with clean, damp cloth</li> <li>• Tubing - wash only if milk or condensation in tubing</li> <li>• Breast pump kit and bottles – wash and sanitize</li> </ul>	<ul style="list-style-type: none"> <li>• Breastpump/case - wipe with clean, damp cloth</li> <li>• Tubing - wash or sanitize only if milk or condensation in tubing</li> <li>• Breastpump kit and bottles – wash and sanitize</li> </ul>
<b>Specifications</b>		
<b>Power Source</b>	100-240 Vac  50/60Hz	100-240 Vac  50/60Hz  0.3A
<b>Batteries</b>	2 x 3.6V/2.2Ah Rechargeable LiON Batteries	2 x 6V/1.2Ah Rechargeable Pb Batteries
<b>Battery charge/discharge</b>	Operation time: approx. 60 minutes Charging time: approx. 4 hours	Operation time: approx. 1 hour Charging time: approx. 4 hours (80%) approx. 8 hours (100%)
<b>Housing Material</b>	Polycarbonate	Polyamide

	<b>Sonata™ (Subject Device), K161725</b>	<b>Symphony™ (Predicate Device), K151632</b>
<b><i>Vacuum aggregate type</i></b>	Linear piston	Diaphragm pump  Two diaphragms - for left and right breast  Linear movement by driving bars
<b><i>Vacuum Regulation type</i></b>	Electronic measuring of the displacement and pressure of the piston which corresponds to the generated vacuum.	Electronic measuring of the displacement of the membranes which corresponds to the generated vacuum.
<b><i>Vacuum range – double mmHg/kPa</i></b>	-50 to -240mmHg $\pm$ 10 mmHg / -7 to -32 kPa $\pm$ 3 kPa (with 21, 24, 27, 30, and 36mm breast shield sizes)	-50 to -250mmHg $\pm$ 20 mmHg / -7 to -33 kPa $\pm$ 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield)  -70 to -250mmHg $\pm$ 20 mmHg / -7 to -33 kPa $\pm$ 3 kPa (with Premie+ Program and 24 mm / size M PersonalFit breastshield)
<b><i>Vacuum range – single mmHg/kPa</i></b>	-50 to -240mmHg $\pm$ 10 mmHg / -7 to -32 kPa $\pm$ 3 kPa (with 21, 24, 27, 30, and 36mm breastshield sizes)	-50 to -250mmHg $\pm$ 20 mmHg / -7 to -33 kPa $\pm$ 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield)  -70 to -250mmHg $\pm$ 20 mmHg / -7 to -33 kPa $\pm$ 3 kPa (with Premie+ Program and 24 mm / size M PersonalFit breastshield)
<b><i>Adjustable Suction Levels</i></b>	10 levels	16 levels
<b><i>Cycling Control Mechanism</i></b>	Electronic measuring of the Motor speed, position and vacuum.	Electronic measuring of the Motor speed and position.
<b><i>Cycle Speed</i></b>	54 – 120 Cycles/Minute	54 – 120 Cycles/Minute (with Standard Program)  35 – 120 Cycles/Minute (with Premie+ Program)

	<b>Sonata™ (Subject Device), K161725</b>	<b>Symphony™ (Predicate Device), K151632</b>
<b>Overflow protection</b>	A Protection Membrane on the kit side acts as a media separation and prevents milk from going into the pump.	A Protection Membrane on the pump side acts as a media separation and prevents milk from going into the pump in case of a milk overflow into the vacuum tubes.
<b>Software</b>	Embedded	Embedded, 2 software cards (Standard 2.0, Preemie+)
<b>Pumping Rhythms</b>	Rhythm 1 and Rhythm 2, each featuring stimulation and expression.	Standard 2.0 or Preemie+ program cards, each featuring stimulation and expression phases.

The technological characteristics of the subject device are different – the subject device utilizes a different vacuum pumping mechanism, has a different user interface, different material components, batteries, dimensions, weight, operating and storage temperature/humidity, suction levels, cycle speeds, and overflow protection mechanisms. However, different types of safety or effectiveness questions are not raised by these differences in technological characteristics.

SUMMARY OF NON-CLINICAL TESTS:

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

- Risk Analysis developed in accordance with ISO 14971:2007 *Medical devices – Application of risk management to medical devices*.
- 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” and concluded that no new testing was required as all patient contacting materials are identical to those used in the predicate Symphony Breast Pump.
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this 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 or engorgement.

- Electrical safety and electromagnetic compatibility testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 standard and IEC 60601-1-2: 2014 standards, respectively
- Safety testing for use in the home per IEC 60601-1-11: 2010 standard
- Performance Testing to determine the vacuum performance, including minimum and maximum vacuum levels for the pump as compared to the predicate device, vacuum stability, battery performance, overflow performance, design life, durability, and acoustic testing.

## CONCLUSION:

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The differences between the Sonata breast pump and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela Inc. concludes that the Sonata breast pump is as safe and as effective as the predicate device and supports a determination of substantial equivalence.