DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 5, 2015

Medela AG
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, WI 53118

Re: K151632
Trade/Device Name: Symphony Breastpump, Symphony Reconditioned, Symphony Preemie+ Breastpump, Symphony Plus Breastpump (battery Version), Symphony Consignment, Preemie Consignment Pump, Symphony Rental, Symphony Plus Rental, Symphony Preemie+ Rental
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: October 2, 2015
Received: October 5 17, 2015

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.

Sincerely yours,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151632

Device Name
Symphony breast pump, Models: Symphony Breastpump, Symphony Preemie+ Breastpump, Symphony Plus Breastpump (battery version), Symphony Consignment, Symphony Preemie Consignment Pump, Symphony Rental, Symphony Plus Rental, Symphony Preemie+ Rental, Symphony Reconditioned

Indications for Use *(Describe)*
The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.

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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510(K) SUMMARY

MEDELA AG

SYMPHONY BREAST PUMP

Medela AG
Symphony Breast Pump

510(k) Summary

K151632

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

DATE: October 30, 2015

SUBMITTER:

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Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Symphony breast pump, Models: Symphony Breastpump, Symphony Preemie+ Breastpump, Symphony Plus Breastpump (battery version), Symphony Consignment, Symphony Preemie Consignment Pump, Symphony Rental, Symphony Plus Rental, Symphony Preemie+ Rental, Symphony Reconditioned

COMMON/USUAL NAME: Powered Breast Pump

DEVICE CLASS: Class II

CLASSIFICATION NAMES: 21 CFR 884.516022 Pump, Breast, Powered

PRODUCT CODE: HGX

PREDICATE DEVICE(S):

K020518 Medela Symphony Breast Pump Model 024

DEVICE DESCRIPTION:

The Symphony breast pump is intended to be used by lactating women to express and collect milk from their breasts. The pumping can be performed on one breast (single pumping) or on both breasts at the same time (double pumping). The Symphony breast pump is a multi-user breast pump and therefore, designed for a safe and hygienic use by different mothers.

The Symphony breast pump employs a control knob for the user to adjust the applied vacuum. The suction patterns are pre-programmed with either constant or variable cycles (pump speed). The Symphony breast pump is capable of providing vacuum levels from -50 to -250 mmHg with cycling rates up to 120 cycles per minute.

The Symphony® breast pump provides the following user features:

- Belt-driven vacuum pump design, for quiet operation.
- Portable or trolley-mounted transport/operation options.
- LCD display, for user assistance/device status.
- Control knob, for user adjustment of vacuum level/pump speed.
- 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.
- Symphony program card with the initiation program (Preemie+) software. The Preemie+ program contains stimulation and expression phases with breast pump suction patterns which assist pump users in the initiation of milk production. The Preemie+ program mimics the irregular sucking pattern of healthy term infants right after birth.
- Symphony program card with the "Standard" pumping program software. The Standard program contains stimulation and expression phases with breast pump suction patterns which assist users in coming to volume, and/or maintenance of lactation. The Standard program imitates a breastfeeding baby during established lactation.
- "Let-down" control button to change between stimulation phase and expression phase.
- Option of either single or double breast pumping.

- Disposable 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.

- A variety of accessories and breast pump kits.

INDICATIONS FOR USE:

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

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

The Symphony breast pump has identical indications for use compared to the previously cleared version (K020518). A number of modifications have been made to the Symphony Breast Pump since the last 510(k) clearance (K020518). These are types of changes expected during years of production, including changes to meet new or modified standards and non-US regulations, manufacturing improvements to increase yield, improve stability and precision of components and prevent damage during use. Changes to the software have also been made, including the introduction of the Preemie+ initiation program.

The table below identifies key similarities and differences of the proposed Symphony breast pump to the legally marketed predicate version of this device (K020518).

TABLE 5.1 COMPARISON OF SYMPHONY TO PREDICATE DEVICE

	Symphony (Current Version)	**Symphony (Predicate Version)** K020518
Indications for Use	The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.	The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.
Environment of Use	Hospital, Home	Hospital, Home

Medela AG
Symphony Breast Pump

	Symphony (Current Version)	**Symphony (Predicate Version)** K020518
User Interface	Hardware interfaces	Hardware interfaces
User Control	State-dependent controls: On-Off membrane switch Let-Down Button (membrane switch), also used to select the Preemie+ initiation program Value-adjustment control: Vacuum/Cycle-adjustment control	State-dependent controls: On-Off membrane switch Let-Down Button (membrane switch) Value-adjustment control: Vacuum/Cycle-adjustment control
Visual Indicator	Liquid-crystal display	Liquid-crystal display
Single/Double Pumping	Single and double pumping	Single and double pumping
Accessories	• Breast shield • Breast shield inserts • Valve • Membrane • Tubing • Bottles, with disks lids and caps • Trolly • Vehicle adapter • Power cord • Container Stand • Cooler • Colostrum and Collection Containers • Pump and Save Bags	• Breast shield • Breast shield inserts • Valve • Membrane • Tubing • Bottles, with disks lids and caps • Trolly • Vehicle adapter • Power cord
Cleaning	• Breastpump/case - wipe with clean, damp cloth • Tubing - wash or sanitize only if milk or condensation in tubing • Breastpump kit and bottles – wash and sanitize	• Tubing - wash or sanitize weekly or if milk or condensation in tubing • Breastpump kit and bottles – wash and sanitize (home) or autoclave sterilization (hospital)
Specifications		
Power Source	100-240 Vac 50/60Hz 0.3A	100-240 Vac 50/60Hz 0.3A

Medela AG
Symphony Breast Pump

	Symphony (Current Version)	**Symphony (Predicate Version)** K020518
Batteries	2 x 6V/1.2Ah Rechargeable Pb Batteries	2 x 6V/1.2Ah Rechargeable Pb Batteries
Battery charge/discharge	Operation time: approx. 1 hour Charging time: approx.. 4 hours (80%) approx.. 8 hours (100%)	Operation time: approx. 1 hour Charging time: approx.. 4 hours (80%) approx.. 8 hours (100%)
Housing Material	Polyamide	PS coated
Vacuum aggregate type	Diaphragm pump Two diaphragms - for left and right breast Linear movement by driving bars	Diaphragm pump Two diaphragms - for left and right breast Linear movement by driving bars
Vacuum Regulation type	Electronic measuring of the displacement of the membranes which corresponds to the generated vacuum.	Electronic measuring of the displacement of the membranes which corresponds to the generated vacuum.
Maximum vacuum mmHg/kPa	Approx. -290 mmHg / -40 kPa	Approx. -290 mmHg / -40 kPa
Vacuum range – double mmHg/kPa	-50 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield) -70 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Preemie+ Program and 24 mm / size M PersonalFit breastshield)	-50 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield)
Vacuum range – single mmHg/kPa	-50 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield) -70 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Preemie+ Program and 24 mm / size M PersonalFit breastshield)	-50 to -250mmHg ± 20 mmHg / -7 to -33 kPa ± 3 kPa (with Standard Program and 24 mm / size M PersonalFit breastshield)
Adjustable Suction Levels	16 levels	16 levels
Cycling Control Mechanism	Electronic measuring of the Motor speed and position.	Electronic measuring of the Motor speed and position.

	Symphony (Current Version)	**Symphony (Predicate Version)** K020518
Cycle Speed	54 – 120 Cycles/Minute (with Standard Program) 35 – 120 Cycles/Minute (with Preemie+ Program)	54 – 120 Cycles/Minute (with Standard Program)
Overflow protection	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.	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.
Software Cards	Standard 2.0 or Preemie+ program cards, each featuring stimulation and expression phases to assist for the initiation, coming to volume, and/or maintenance of lactation. Vacuum range and cycle speed are dependent on the breast pump suction patterns. The Standard 2.0 program consists of two different curves. The Preemie+ initiation program consists of three different curves: Standard 2.0 program card: Standard program only. Preemie+ program card: Standard 2.0 and Preemie+ programs.	Standard program card featuring stimulation and expression phases to assist for the coming to volume, and/or maintenance of lactation. Vacuum range and cycle speed are dependent on the breast pump suction patterns. The Standard program consists of two different curves. The Standard program card includes the Standard program only

SUMMARY OF NON-CLINICAL TESTS:

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

- Risk Analysis developed in accordance with ISO 14971: 2007.
- Sterilization information in accordance with FDA's guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

- Cleaning Validation. Validation of cleaning methods, both manual cleaning with dish soap and cleaning in the dishwasher, and validation of the sanitation process with boiling water and the quick clean™ micro-steam™ bags were conducted. A selection of reusable breast pump kit components that contact breast milk representative of all Medela breast pump components, including those specified for use with Symphony, were challenged with a human breast milk solution containing organisms, cleaned, or sanitized according to the Instructions for Use and evaluated for the presence of surviving organisms. The validation protocol was based upon AAMI TIR30-2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 8 October 2003.
- For sterile items, accelerated aging tests to support the labeled shelf life were conducted according to ASTM F1980 (07) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Testing was also conducted to verify drive unit life time in support of the breast pump service life specification.
- 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: 2007 standards, respectively
- Safety testing for use in the home per IEC 60601-1-11: 2010 standard
- Performance testing demonstrating compliance with EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment
- Performance testing at minimum and maximum vacuum settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications, which are identical to those of the predicate version of the Symphony pump. Tests were conducted over 20 minutes with the Standard 2.0 program card or 15 minutes with the Preemie+ program card to simulate a typical pumping session using size medium (M) breast shields. Tests began in stimulation mode and continued with expression mode after the first two minutes. There are two approved suppliers of the motor for the Symphony® breast pump. Testing of six pumps was completed with the Standard 2.0 program card, using three pumps with each motor type. One of each pump type was used for testing with the Preemie+ program card. Vacuum performance during normal use was first evaluated and demonstrated that, independent of the pump

motor type, the specification for vacuum level and cycle rate is met. Additional test cases evaluated performance of the pump when running on battery, performance with varying input voltages and with the other size breast shields. Finally, testing of performance for single pumping was completed. Results demonstrated that independent of the pump motor type, the specification for battery operation time is met, that the specification for vacuum level and cycle rate is met in single pumping mode as well as with all power source and with varying input voltage. With different breast shield sizes, the specification for the maximum vacuum level is met.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Symphony breast pump to its predicate device. However, published research studies are referenced to support marketing claims.

CONCLUSION:

The differences between the Symphony 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 AG concludes that the Symphony breast pump is substantially equivalent to the legally marketed predicate device.