DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 29, 2016

Philips Consumer Lifestyle-Innovation Site Eindhoven
Marta Walker
Sr. Safety, Compliance & Regulatory Manager
High Tech Campus 37
Eindhoven, 5656 AE
Netherlands

Re: K161532
Trade/Device Name: Philips Avent Comfort Single/Twin Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 29, 2016
Received: June 2, 2016

Dear Marta Walker:

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)*
K161532

Device Name

Philips Avent Comfort Single/Twin Electric Breast Pump

Indications for Use *(Describe)*

The Philips Avent Comfort Single/Twin Electric Breast Pump is intended to express and collect milk from the breast of a lactating woman. The device 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.

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Department of Health and Human Services
Centre of Devices and Radiological Health
Office of Device Evaluation
Traditional 510(k) section 10

510(K) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION as required by section 21 CFR 807.92

K161532

1. SUBMITTER OF 510(K):

Company name:	Philips Consumer Lifestyle - Innovation Site Eindhoven
Registration number:	3009226815
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e-mail:	marta.walker@philips.com
Correspondent	Marta Walker, Sr. Manager Safety, Compliance & Regulatory
Date of Preparation:	August 8th, 2016

2. DEVICE(S):

Trade / Proprietary Name:	Philips Avent Comfort Single/Twin Electric Breast Pump
Common / Usual Name:	Powered Breast Pump
Regulation Name:	Obstetrics/Gynecology
Classification Name:	Powered Breast Pump
Classification:	21 CFR 884.5160, Class II
Product Code:	HGX

3. PREDICATE DEVICE(S):

Philips devices are based on the legally marketed devices cited in Table below:

Table 1: Predicate Device

Manufacturer	Device	510(k) #	Product Code:
Medela Ag	Freestyle Deluxe, Freestyle Solution Set, Freestyle Basic, Freestyle Motor Warranty	K150499	HGX

4. DEVICE DESCRIPTION:

The Philips Avent Comfort Single/Twin Electric Breast Pump is intended to express and collect milk from the breast of a lactating woman. The device is intended for a single user.

The subject devices are electrically powered single (Comfort Single) and double (Comfort Double) breast pumps consisting of a motor and pump body, press-button user interface, and collection kit. A vacuum pump creates a vacuum at the breast of the lactating woman. This vacuum is released after a short period of time. By repeating this behavior, a cyclic vacuum generation pattern is created which enables expressing of milk from the breast. The expressed milk will be collected in the container which can be used for storage.

The breast pump supports different operating modes: stimulation, expression 1, expression 2 and expression 3. The stimulation mode is entered upon start of the device when suction is felt on the breast. Once the milk starts flowing an expression mode may be chosen that has the most comfort, e.g. the combination of rhythm and suction level.

5. INDICATION FOR USE:

The Philips Avent Comfort Single/Twin Electric Breast Pump is intended to express and collect milk from the breast of a lactating woman. The device is intended for a single user.

The indications for use for the subject and predicate devices are comparable (see Table 3), and the intended use of the subject and predicate devices are the same as they are both for use in expressing and collecting milk from the breast of a lactating woman.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of these devices are similar to those of the predicate device (Medela Free Style K150499).

A comparison of the basic characteristics of the Philips Avent Comfort Single/Twin Electric Breast Pump and of the Medela Freestyle BreastPump (K150499) is presented in Table 3.

Table 3: Substantial Equivalence Comparison Table

Parameter	Philips Avent Comfort Single/Twin Electric Breast Pump	**Medela Freestyle BreastPump (K150499)**
Indications for Use	The Philips Avent Comfort Single/Twin electric breast pump is intended to express and collect milk from the breast of a lactating women. The device is intended for a single user.	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.
Intended Use	Express and collect milk	Express and collect milk
Single User Device	Yes	Yes
Environment of Use	Home	Home

User Interface	Hardware Interfaces	Hardware Interfaces
User Control	On-off switch Vacuum/Cycle-adjustable control	On-off switch Vacuum/Cycle-adjustable control
Visual Indicator	LED Lights	LCD Display
Pumping Options	Single or Double	Single or Double
Specifications		
Power Supply	AC-Adapter provided or 4xAA batteries	Li-ion battery or AC-Adapter provided
Suction levels (stimulation)	127mmHg +/- 15mmHg	40 – 140mmHg
Cycles per second (stimulation)	1.42 – 2.0	1.7 – 1.93
Suction levels (expression)	168 – 250mmHg	45 – 245mmHg
Cycles per second (expression)	0.70 – 0.87	0.83 – 1.36
Maximum Vacuum	250mmHg	270mmHg
Adjustable suction levels	Yes	Yes
Let-down button	Yes	Yes
Cycling control mechanism	Microcontroller	Microcontroller
Backflow protection	Yes	Yes
2-Phase Expression	Yes	Yes

The subject and predicate device have similar technological characteristics. The most relevant differences between the two devices are as follows:

- Power Supply – the subject devices use an AC adaptor (Comfort Single and Twin) or AA batteries (Comfort Single only). The predicate uses both an AC adaptor and lithium ion batteries. This does not raise different questions of safety and effectiveness as AA batteries have a lower capacity than Li-ion batteries.
- Suction Levels – The upper limit of the expression suction levels is slightly higher in the subject device and the range is smaller compared to the predicate. These slight differences in suction levels do not raise different questions of safety and effectiveness as compared to the predicate device.
- Cycles per Second – The range of stimulation cycles per second is slightly larger than the predicate device, while the range of expression cycles per second is slightly smaller. This does not raise different questions of safety and effectiveness as the clinical significance of the minor differences in cycles per second is negligible.
- Visual Display – The subject device uses LED lights to display user interface buttons while the predicate device uses an LCD screen. This does not raise different questions of safety and effectiveness as the usability of the subject device should not be affected.

As discussed above, the technological differences do not raise different questions of safety or effectiveness, and accepted test methods exist to assess the effects of these differences on device performance.

7. PERFORMANCE TESTING

Verification and validation activities were designed and performed to support the substantial equivalence of this devices and the predicate device. The following performance data was provided:

7.1. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was conducted on the Philips Comfort Single/Twin Electric Breast Pump . The device complies to the following standards:

AAMI / ANSI ES60601-1:2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
AAMI / ANSI / IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

7.2. Software Verification and Validation

Software verification and validation testing was conducted complying to:

AAMI / ANSI / IEC 62304:2006	Medical device software – Software life cycle processes

Documentation was also provided according to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

7.3. Usability Testing

Usability testing was conducted according to the FDA Guidance 1497, Medical Device Use-Safety Incorporating Human Factors into Risk Management. This testing demonstrated that the usability of the subject device is substantially equivalent to the predicate device.

7.4. Biocompatibility Testing

Biocompatibility testing was conducted following the FDA Blue Book Memorandum "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and according to the following standards:

ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ANSI / AMI / ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

The biocompatibility testing demonstrated that the patient contacting materials are biocompatible.

7.7. Vacuum Performance Test

Performance testing to determine the vacuum performance, including minimum and maximum vacuum levels for the pump as compared to the predicate device, vacuum stability, durability and pump temperatures during operation.

The vacuum performance testing demonstrated the mechanical performance and performance specifications of the subject device. The testing validated that the performance of the subject device is substantially equivalent to the predicate device.

9. CONCLUSION

The differences between the Philips Avent Comfort Single/Twin Electric Breast Pump and its predicate device Medela Freestyle (K150499) do not introduce a new intended use and do not represent new technological characteristics raising different questions of safety and effectiveness as compared to the predicate device.
From the results of nonclinical testing described, Philips concludes that the Philips Avent Comfort Single/Twin Electric Breast Pump is substantially equivalent to the legally marketed predicate device.