October 1, 2020

Philips Consumer Lifestyle - Innovation Site Eindhoven
Aurore Millet
Senior Regulatory Affairs Manager
High Tech Campus 37
Eindhoven, 5656 AE
NETHERLANDS

Re: K201381
Trade/Device Name: Philips Avent Single/Double electric breast pump Advanced
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: August 31, 2020

Dear Aurore Millet:

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,

For
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)*
K201381

Device Name
Philips Avent Single/Double electric breast pump Advanced

Indications for Use *(Describe)*
The Philips Avent single/double electric breast pump Advanced is intended to express and collect milk from the breast of a lactating woman, and to alleviate engorgement of the breast. 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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510(k) SUMMARY
K201381

1 Submitter Information

Company Name:	Philips Consumer Lifestyle - Innovation Site Eindhoven
Address:	High Tech Campus 37 Eindhoven 5656 AE The Netherlands
Contact Person:	Aurore Millet Senior Regulatory Manager + 31 6 181 91 888 aurore.millet@philips.com
Date of preparation:	September 30, 2020

2 Device Information

Trade/Device Name:	Philips Avent Single/Double electric breast pump Advanced
Common /Usual Name:	Powered Breast Pump
Regulation Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	II

3 Predicate Device Information

K161532
Manufacturer: Philips Electronics UK Limited
Device Name: Philips Avent Comfort Single/Twin Electric Breast Pump

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

4 Device Description

The Philips Avent Single/Double electric breast pump Advanced 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 for repeated use by a single user and are for use in home and professional healthcare environments. The devices are not sterile.

The subject devices are electrically powered single (Single Advanced) and double (Double Advanced) breast pumps consisting of the following key components: a motor unit with a press-button user interface, and expression kit with milk collection container (double pump: two kits and containers) connected with the motor unit via a silicone tube. The motor unit operates on embedded software. Software updates by end-users are not supported.

The breast pump extracts milk from the breasts by creating a seal around the nipple and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, the expression kit includes a silicone diaphragm that physically separates the milk-contacting pathway from the vacuum system.

The motor unit operates on an external mains adapter that is provided with the system via a micro-USB type connection. Models SCF392 and SCF394 include a rechargeable battery that can be used for device operation. The rechargeable battery can be charged from the external mains adapter if the motor unit is not in operation.

The expression kit is provided in two types: cushion-type and flange-type.

The cushion-type expression kit has a silicone cushion which is mounted on the expression kit pump body. The cushion comes into contact with the breast for the duration of the expression session.

In the flange-type expression kit, the silicone cushion is integrated in a rigid frame. This integrated part (flange) can be attached to the pump body with a screw connection. The silicone part comes into contact with the breast for the duration of the expression session. The rigid frame is not in contact with the breast.

All other components of the subject devices are not in contact with the breast.

The subject device versions are shown in the table below:

Trade/Device Name	Number of pumps	User Interface	Battery	Expression kit type	Model Identification
Philips Avent Single electric breast pump Advanced	1 (**Single** electric)	4 buttons and 8-dot display	No battery	Cushion	SCF391/61
				Flange	SCF391/62
		4 buttons and 2-digit display	With battery	Cushion	SCF392/61
				Flange	SCF392/62
Philips Avent Double electric breast pump Advanced	2 (**Double** electric)	4 buttons and 8-dot display	No battery	Cushion	SCF393/61
				Flange	SCF393/62
		4 buttons and 2-digit display	With battery	Cushion	SCF394/61
				Flange	SCF394/62

The subject devices consist of the following materials:

- Motor unit: ABS, mABS, HTV Silicone
- Cushion, tube, milk valve, diaphragm: Silicone

- Pump body, milk collection container: Polypropylene
- Flange: Polypropylene, Polybutylene Terephthalate, Silicone

All milk contacting components are compliant with 21 CFR 174-179, 21 CFR 177.1520 and 21 CFR 177.2600.

5 Indications for Use

The Philips Avent single/double electric breast pump Advanced is intended to express and collect milk from the breast of a lactating woman, and to alleviate engorgement of the breast. The device is intended for a single user.

6 Comparison of Intended Use and Technological Characteristics with the Predicate Device

	Subject Device **Philips Avent Single/Double electric breast pump Advanced (K201381)**	**Predicate Device** **Philips Avent Comfort Single/Twin Electric Breast Pump (K161532)**
Product Name	*Versions without battery:* Single electric breast pump Advanced (SCF391/61 and SCF391/62) Double electric breast pump Advanced (SCF393/61 and SCF393/62) *Versions with battery:* Single electric breast pump Advanced (SCF392/61 and SCF392/62) Double electric breast pump Advanced (SCF394/61 and SCF394/62)	Comfort Single SCF332/11 Comfort Twin SCF334/12 Comfort Twin SCF334/13 Comfort Twin SCF334/14 Comfort Twin SCF334/15
Manufacturer	Philips Consumer Lifestyle BV Tussendiepen 4 9206 AD, Drachten The Netherlands	Philips Electronics UK Limited LOWER ROAD GLEMSFORD Suffolk, GB CO10 7QS
Product Code	HGX	HGX
Regulation No.	21 CFR 884.5160	21 CFR 884.5160
Class	Class II	Class II
Patient Population	Lactating women	Lactating women
Environment of Use	Home healthcare environment	Home healthcare environment

	Subject Device **Philips Avent Single/Double electric breast pump Advanced (K201381)**	**Predicate Device** **Philips Avent Comfort Single/Twin Electric Breast Pump (K161532)**
Indications for Use	The Philips Avent single/double electric breast pump Advanced is intended to express and collect milk from the breast of a lactating woman, and to alleviate engorgement of the breast. The device is intended for a single user.	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.
Pump options	Single or double pumping	Single or double pumping
Backflow Protection	Yes (Silicone diaphragm on the expression kit, which separates the vacuum system of the motor unit from milk-contacting parts)	Yes (Silicone diaphragm on the expression kit, which separates the vacuum system of the motor unit from milk-contacting parts)
Suction modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode
Transition between suction modes	Automatic or manual	Manual
Adjustable suction levels	Yes	Yes
Vacuum range Stimulation	-45 to -150 mmHg	127 ± 15 mmHg
Vacuum range Expression	-45 to -270 mmHg	-168 to -250 mmHg
Cycle speed (stimulation mode)	105 to 120 cycles/min	85 to 120 cycles/min
Cycle speed (expression mode)	53 to 85 cycles/min	42 to 53 cycles/min
Controls	4 Buttons (On-Off-Pause-Resume, Stimulation or Expression mode, Decrease vacuum level, Increase vacuum level)	On-off switch Vacuum/Cycle-adjustable control
Indicators	LED indicators: 8-dot display (versions without battery) 2-digit 7-segment display (versions with battery)	LED Lights
Power connection	Micro-USB (power only)	Pin

	Subject Device **Philips Avent Single/Double electric breast pump Advanced (K201381)**	**Predicate Device** **Philips Avent Comfort Single/Twin Electric Breast Pump (K161532)**
Power supply	AC-Adapter provided (100-240 V primary and 5 V secondary) or Lithium- ion battery 3.6 V 2600 mAh (for battery-operated devices)	AC-Adapter provided (100-240 V primary and 5 V secondary (Comfort Single); 9 V secondary (Comfort Twin)) or 4xAA batteries (Comfort Single only)

The indications for use of the subject and predicate device are similar. In comparison to the predicate device, the subject device has an extended indication: "and to alleviate engorgement of the breast". However, the intended use of the subject and predicate devices is the same (express and collect milk from the breast of a lactating woman).

The subject and predicate devices have different technological features, including design, user interface, vacuum pressure range, cycle speeds, and power source. These technological differences do not raise different questions of safety and effectiveness.

7 Summary of Non-Clinical Performance Testing

The Philips Avent Single/Double Electric Breast Pump Advanced complies with recognized consensus standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment, software, biocompatibility, Lithium-Ion Battery Testing. The following performance data were provided to support the substantial equivalence determination:

- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text).
- Electrical Safety Testing for use in the home in accordance with IEC 60601-1-11 Edition 2.0 2015-01.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- Software Verification and Validation Testing as recommended in the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).
- Biocompatibility Tests in accordance with ISO-10993, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).
- Lithium-Ion Battery Testing according to the IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
- Backflow protection testing, Vacuum/cycle performance testing, and use-life testing.

8 Conclusion

The performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and supports a determination of substantial equivalence.