December 15, 2020

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

Re: K203383
Trade/Device Name: Philips Avent Double electric breast pump Advanced SCF394/61
Philips Avent Double electric breast pump Advanced SCF394/62
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: Class II
Product Code: HGX
Dated: November 13, 2020
Received: November 17, 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 Garcia
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)*
K203383

Device Name
Philips Avent Double electric breast pump Advanced SCF394/61, Philips Avent Double electric breast pump Advanced SCF394/62

Indications for Use *(Describe)*
The Philips Avent 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 – K203383

1. Submitter Information

Applicant: Philips Consumer Lifestyle - Innovation Site Eindhoven
Address: High Tech Campus 37
Eindhoven 5656 AE
The Netherlands

2. Correspondent Information

Contact: Aurore Millet
Senior Regulatory Manager
Phone: +31 6 181 91 888
Email: aurore.millet@philips.com

3. Date prepared: December 11, 2020

4. Device Information

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

5. Predicate Device Information

Device Name:	Philips Avent Double electric breast pump Advanced
510(k) Number:	K201381
Manufacturer:	Philips Consumer Lifestyle BV
Product Code:	HGX (Pump, Breast, Powered)

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

6. Device Description

The Philips Avent 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 double (Double Advanced) breast pumps consisting of the following key components: a motor unit with a press-button user interface, two expression kits with two milk collection containers connected with the motor unit via silicone tubes. 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 a rechargeable battery or on an external mains adapter that is provided with the system via a micro-USB type connection. The rechargeable battery can be charged from the external mains adapter if the motor unit is not in operation.

The breast pump is provided with the same accessories as the predicate device (K201381), with the addition of a breast pump belt. The breast pump belt intended to carry the electrical breast pump while the device is used to express and collect milk. The belt is intended to be worn over clothes.

The expression kit is provided in two types: cushion-type (SCF394/61) and flange-type (SCF394/62).

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.

Table 1: Subject Device variants

Trade/Device Name	**Number of pumps**	**User Interface**	**Battery**	**Expression kit type**	**Model Identification**
Philips Avent Double electric breast pump Advanced	2	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.

7. Indications for Use

The Philips Avent 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.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject and Predicate Devices

	Philips Avent Double electric breast pump Advanced K203383 Subject Device	**Philips Avent Double electric breast pump Advanced K201381 Predicate Device**	**Comparison**
Product Name	Double electric breast pump Advanced (SCF394/61 and SCF394/62)	Double electric breast pump Advanced (SCF394/61 and SCF394/62)	**Same**
Manufacturer	Philips Consumer Lifestyle BV Tussendiepen 4 9206 AD, Drachten The Netherlands	Philips Consumer Lifestyle BV Tussendiepen 4 9206 AD, Drachten The Netherlands	**Same**
Product Code	HGX	HGX	**Same**
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	**Same**
Class	Class II	Class II	**Same**
Patient Population	Lactating Women	Lactating Women	**Same**
Environment of use	Home Healthcare Environment	Home Healthcare Environment	**Same**
Indications for Use	The Philips Avent 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 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.	**Same**
Pump Options	Double	Single or Double	**Similar:** The affected models of the predicate are exclusively 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)	**Same**
Suction Modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode	**Same**
Transition between suction modes	Automatic or Manual	Automatic or Manual	**Same**
Adjustable suction levels	Yes	Yes	**Same**
Vacuum range: Stimulation	-45 to -150 mmHg	-45 to -150 mmHg	**Same**
Vacuum range: Expression	-45 to -270 mmHg	-45 to -270 mmHg	**Same**
Cycle Speed: Stimulation	105 to 120 cycles/min	105 to 120 cycles/min	**Same**
Cycle Speed: Expression	53 to 85 cycles/min	53 to 85 cycles/min	**Same**
Controls	4 Buttons (On-Off-Pause-Resume, Stimulation or Expression mode, Decrease	4 Buttons (On-Off-Pause-Resume, Stimulation or Expression mode, Decrease	**Same**

	vacuum level, Increase vacuum level)	vacuum level, Increase vacuum level)	
Indicators	LED indicators: 8-dot display (versions without battery) 2-digit 7-segment display (versions with battery)	LED indicators: 8-dot display (versions without battery) 2-digit 7-segment display (versions with battery)	**Same**
Power connection	Micro-USB (power only)	Micro-USB (power only)	**Same**
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) or Lithium- ion battery 3.6 V 2600 mAh (for battery-operated devices)	**Same**
Accessories	Pump body Cushion Flange Slave cap Membrane Tube Milk valve 4oz bottle Breast shield cover Screw ring Sealing disc Teat (nipple) Dormal cap Pouch Travel bag Disposable breast pads Breast pump belt	Pump body Cushion Flange Slave cap Membrane Tube Milk valve 4oz bottle Breast shield cover Screw ring Sealing disc Teat (nipple) Dormal cap Pouch Travel bag Disposable breast pads	**Different:** The subject device is packaged with a breast pump belt accessory. Through performance testing validation it was determined that the accessory does not raise additional questions of substantial equivalence.

The indications for use of the subject and predicate device are identical.

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

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Skin Irritation Testing, Cytotoxicity, and Skin Sensitization testing were performed in accordance with the 2016 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

The testing supports the biocompatibility of the device.

10. 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.