



November 3, 2023

Evenflo Feeding, Inc.
Michael Sewak
Director of Quality
9277 Centre Pointe Drive, Suite 160
West Chester, OH 45069

Re: K230481
Trade/Device Name: Evenflo Premium Double Electric Breast Pump (Model 4018)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: October 1, 2023
Received: October 3, 2023

Dear Michael Sewak:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.

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

Indications for Use

510(k) Number (if known)
K230481

Device Name
Evenflo Premium Double Electric Breast Pump (Model 4018)

Indications for Use (Describe)

The Evenflo Premium Double Electric Breast Pump (Model 4018) is an electrically powered suction device intended to express and collect milk from a lactating woman's breasts. It 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 – K230481

1. Submitter Information

Applicant: Evenflo Feeding, Inc.
Phone: (513) 870-1620
Address: 9277 Centre Pointe Drive, Suite 160
West Chester, OH 45069.

2. Correspondent Information

Contact: Michael Sewak
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Phone: Office Phone: (513) 745-4625
Mobile Phone: (513) 773-8188

3. Date prepared: November 1, 2023

4. Device Information

Device Name: Evenflo Premium Double Electric Breast Pump (Model 4018)
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: Evenflo Model 2951 Advanced Double Electric Breast Pump
510(k) Number: K131153
Manufacturer: Evenflo Feeding Inc.

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

6. Device Description

The Evenflo Electric Breast Pump (Model 4018) is an electrically powered breast pump to be used in a home environment by a single user. The device is provided non-sterile and should be cleaned and disinfected prior to first use according to the instructions for use. The breast pump can be used on one breast (single pumping) or on both breasts at the same time (double pumping).

The device consists of a pump unit, AC power adapter, power cable, AdvancedFit flange kit and bottle kit. The AdvancedFit flange kit consists of a flange body, flange insert, check valve (valve and membrane), diaphragm, diaphragm cap, and tubing for each breast, a tubing adapter to connect the kit to the pump unit and a tubing adapter plug to convert for single pumping. It does not incorporate off-the-shelf (OTS) software or wireless technology/mobile app software functionality. The pump is powered by an internal, non-replaceable, rechargeable lithium-ion battery which is charged using the included AC power supply and cable. The subject device can be operated while plugged into AC power.

The breast pump uses cyclic negative pressure (suction) to mimic the suckling patterns of a feeding infant. A DC motor drives a membrane vacuum pump to generate the suction required to stimulate and express breast

milk. The timing of this pattern is dependent upon the suction/speed settings selected by the user and is pre-programmed in the device. The device is capable of producing peak suction levels between -50 and -250 mmHg in double pumping mode and between -85 and -250 mmHg in single pumping modes at speeds between 30 and 80 cycles per minute. There are 9 distinct levels of suction and 6 speeds available for each suction level.

The breast pump expresses breast milk by creating a seal around the nipple using a flange 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, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

All other components (i.e., motor unit) of the subject device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Evenflo Premium Double Electric Breast Pump (Model 4018) is an electrically powered suction device intended to express and collect milk from a lactating woman’s breasts. It 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 1: Comparator Table for Subject and Predicate Devices

	Evenflo Premium Double Electric Breast Pump, Model 4018 K230481 Subject Device	Evenflo Model 2951 Advanced Double Electric Breast Pump K131153 Predicate Device	Comparison
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Regulatory Class	Class II	Class II	Same
Patient Population	Lactating Women	Lactating Women	Same
Indications for Use	The Evenflo Premium Double Electric Breast Pump (Model 4018) is an electrically powered suction device intended to express and collect milk from a lactating woman’s breasts. It is intended for a single user.	The Evenflo Advanced Double Electric Breast Pump is an electrically powered suction device intended to express and collect milk from lactating woman’s breasts. It is intended for a single user.	Same Intended Use
Pump Options	Single or Double	Single or Double	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Backflow Protection	Yes	Yes	Same
Mobile Application	No	No	Same
Indicators	Yes, (2) 7-segment Digits (Suction & Speed)	(12) Discrete LEDs (8 Suction, 4 Speed)	Different. Differences in user interface/indicators do not raise different questions of safety and

			effectiveness.
Single User	Yes	Yes	Same
Media separation (backflow protection)	Yes	Yes	Same
Expression pattern	2-Phase	2-Phase	Same
Suction levels (Single pumping)	85-250 mmHg	25-270 mmHg	Different. Differences in massage suction levels do not raise different questions of safety and effectiveness
Suction levels (Double pumping)	50-250 mmHg	25-254 mmHg	Different. Differences in pumping suction levels do not raise different questions of safety and effectiveness
Cycles per Minute	30-80 cpm	30-80 cpm	Same
Suction levels	9 vacuum levels	8 vacuum levels	Different. Differences in available suction levels do not raise different questions of safety and effectiveness.
User Interface	8 pushbuttons	4 pushbuttons	Different. Differences in user interface do not raise different questions of safety and effectiveness.
Adjustable Suction Levels	Yes	Yes	Same
Design	Tabletop Milk Collector and Flange	Tabletop Milk Collector and Flange	Same
Included Accessories	Flanges, Soft Flange Inserts, Bottles, Tubing Check valves, Diaphragms, Bottle Stands	Flanges, Soft Flange Inserts, Bottles, Tubing Check valves, Diaphragms	Similar
Power Supply	7.4 VDC 2200 mAh Battery	6 X AA (LR6) Primary Battery	Different. Differences in available power supply do not raise different questions of safety and effectiveness as performance is independently assessed for each available power configuration.

The indications for use of the subject and predicate device are similar, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including available accessories, cycle speed levels, and overall design. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum specifications, power supply, user interface, and vacuum levels. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies on the patient-contacting components of the subject device, including irritation, cytotoxicity, and sensitization testing were performed in accordance with the 2020 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”, as follows:

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

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety

Testing was conducted in accordance with ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), IEC 62133-2:2017, 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, and IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Electromagnetic Compatibility

Testing was conducted in accordance with IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

Software

Software was evaluated for a minor level of concern as recommended in the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

10. Conclusion

The results of the performance testing described above demonstrate that the Evenflo Premium Double Electric Breast Pump (Model) 4018 is as safe and effective as the predicate device and supports a determination of substantial equivalence.