August 4, 2023

Annabella Ltd.
% Dalia Dickman, Ph.D.
Regulatory Consultant
Dalia Dickman Consulting
Manof
Misgav, 20184
Israel

Re: K230672
Trade/Device Name: Annabella Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 6, 2023
Received: July 7, 2023

Dear Dalia Dickman:

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230672

Device Name
Annabella Breast Pump

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Annabella Tech Ltd's Annabella Breast Pump

Submitter

Annabella Tech Ltd.
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Contact Person: Dalia Dickman, PhD.

Date Prepared: August 2, 2023

Device Name: Annabella Breast Pump

Common or Usual Name: Powered breast pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered breast pump

Regulatory Class: II

Product Code: HGX (Powered, Breast, Pump)

Predicate Device

Medela Freestyle (K150499)

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

Device Description

The Annabella Breast Pump is a single, electric breast pump system intended to express and collect milk from the breasts of lactating women. It is comprised of a vacuum unit including tubing and a massage unit that mimics the baby's sucking motions. The user employs buttons on the vacuum unit to control the vacuum intensity levels, suction rate as well as the massage unit speed and location on the breast. The device is supplied with a reusable, washable and adjustable breast shield, a bottle, bottle lids and a charger. The Annabella is a rechargeable Li-ion battery operated device that contains software. The device cannot be operated while connected to the mains AC Power core.

The battery compartment is at the bottom of the pump motor unit and is covered by a battery door. The runtime of the removable lithium-ion battery is influenced by the number and duration of pumping sessions and lasts usually for one day.

The device is to be used in the home.

Intended Use / Indications for Use

The Annabella Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella Breast Pump is intended for a single user.

Predicate Device Comparison

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

Device Name	**Annabella Breast Pump**	**Predicate Device: FreeStyle; K150499**	**Discussion**
Indications for Use	The Annabella Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella Breast Pump is intended for a single user.	The Freestyle® is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle® is intended for a single user.	Identical
Intended Use	Express and collect milk	Express and collect milk	Identical
Single User Device	Yes	Yes	Identical
Environment of Use	Home	Home	Identical
Over the Counter	Yes	Yes	Identical
User Interface Hardware Interfaces			
User Control	• On-off switch • Vacuum adjustment Control • Cycle-adjustment Control • Tongue mechanism	On-off switch Vacuum/Cycle-adjustment control	Different – Annabella has two independent controls for vacuum and cycles. Freestyle® uses a single control to adjust vacuum and cycles together.

	control (height and pace)		
Visual Indicator	7 Segment Display and LED Indications	LCD Display	Different – Both provide indications display
Pumping Options	Single only	Single or Double	Different – Pumping mechanism is the same
Accessories	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying • Cleaning • Feeding	Different – both systems come with or make available a variety of accessories that can be used with the pump for collection and storage of breast milk, providing power and breast pump. Freestyle® has additional accessories for carrying and cleaning its components and feeding stored milk.
Media Separation	Yes	Yes	Identical
Specifications			
Power Supply	• Li-Ion battery or • AC adaptor provided	• Li-Ion battery or • AC adaptor provided	Identical
Suction Levels (stimulation)	27-105 mmHg	40 - 140 mmHg	Different
Cycles per second (stimulation)	1.66-2.0	1.7-1.93	Different
Suction Levels	26-217 mmHg	45 – 245 mmHg	Different

(expression)			
Cycles per second (expression)	0.8-1.44	0.83-1.36	Different
Maximum Vacuum	250 mmHg	270 mmHg	Different
Suction Settings	9	9	Identical
Adjustable Suction Levels	Yes	Yes	Identical
Let-Down Button	Yes	Yes	Identical
Massage (Tongue Mechanism)	– 4 cams rotating at a typical angular speed of 0-40rpm – 9 levels of speed – 9 levels for location on the breast (distance from the breast center)	NA	Annabella has an additional massage unit – both the speed and location on the breast is controlled by the user for maximum comfort; the user can stop its operation at any time. The addition of the massage unit does not raise different questions of safety and effectiveness.
Cycling Control Mechanism	Microcontroller	Microcontroller	Identical
Back Flow Protection	Yes	Yes	Identical
2-phase expression	Yes	Yes	Equivalent. Both devices offer an initial simulation phase that moves to expression phase after two

			minutes.

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

The subject and predicate devices have different technological features, including differences in the pumping options, cycle speeds, vacuum strengths, visual indicators, and the inclusion of a massage unit in the subject device. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

Performance Data

Non-clinical tests were conducted to verify that the subject device met all design specifications to be considered substantially equivalent to the predicate device.

Electrical Safety and Electromagnetic Compatibility:

- Electrical Safety Testing was performed in accordance with IEC 60601-1:2005 (3rd Edition)
- Electrical safety testing for use in home was performed in accordance with IEC 60601-1-11:2015, 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.
- Battery safety testing was performed in accordance with the applicable standards for Lithium-ion batteries: Cell and pack: 62133-2:2017-02: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- Electromagnetic compatibility testing was performed in accordance with IEC 60601-1-2:2021. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Software Verification:

Software Verification was performed in accordance with IEC 62304:2015 Ed.1.1: Medical Device Software – Software Life Cycle Processes and according to the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

Biocompatibility:

Biocompatibility evaluation was performed according to the following requirements of ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process for patient-contacting components of the subject device as follow:

- Cytotoxicity testing per ISO 10993-5:2009
- Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
- Irritation testing per ISO 10993-10:2010

Non-clinical Performance Testing:

- Vacuum level/suction strength of subject devices was tested for each mode/ cycle.
- Backflow protection testing was conducted to ensure that even if the bottle is over-filled, no liquid will backflow into the tubing, and therefore no liquid can backflow into the pump motor.
- Cycle speed of subject devices was tested.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.
- Device use life to demonstrate that the device maintains its specifications throughout its proposed use life.

Conclusions

The results of the performance testing described above demonstrate that the Annabella Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.