June 27, 2024

Annabella Tech
% Dalia Dickman
Regulatory Consultant
Dalia Dickman Consulting
Caesarea
ISRAEL

Re: K241506
Trade/Device Name: Annabella Double Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 23, 2024
Received: May 28, 2024

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 (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,
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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)*
K241506

Device Name
Annabella Double Breast Pump

Indications for Use *(Describe)*
The Annabella Double Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella Double 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 – K241506

Annabella Tech Ltd's Annabella Double Breast Pump

Submitter

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Contact Person: Dalia Dickman, PhD.

Date Prepared: May 23, 2023

Device Name: Annabella Double 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

Annabella Breast Pump (K230672)

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

Device Description

The Annabella Double Breast Pump is a double, electric breast pump system intended to express and collect milk from the breasts of lactating women. Each pump is comprised of a vacuum unit including tubing (connected to a hybrid cable with a "Y" connector) and a massage unit (tongue mechanism) that mimics the baby's sucking motions. The Y hybrid cable delivers the vacuum from the vacuum unit through the Y splitter to both massage units. 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 Double Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella Double 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.

	Subject Device: Annabella Double Breast Pump	**Predicate Device: Annabella Breast Pump (K230672)**	**Discussion**
Intended Use/ Indication for use	The Annabella Double Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella is intended for a single user.	The Annabella is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Annabella 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/Cycle-adjustment control. Massage adjustment control- speed and location relative to the breast center.	On-off switch Vacuum/Cycle-adjustment control. Massage adjustment control- speed and location relative to the breast center.	Identical
Visual Indicator	7 Segment Display and LED Indications	7 Segment Display and LED Indications	Identical
Pumping options	Single or double	Single	Different – The subject device has two single and pumping options. The pumping mechanism is the same for both devices.
Media Separation	Yes	Yes	Identical
Specifications			
Power Supply	Li-Ion rechargeable battery	Li-Ion rechargeable battery	Identical
Suction Levels	Stimulation: 30 - 122	Stimulation: 35 - 130	Different; there

	Subject Device: Annabella Double Breast Pump	**Predicate Device: Annabella Breast Pump (K230672)**	**Discussion**
	mmHg Expression: 39 -250 mmHg	mmHg Expression: 33 -250 mmHg	are minor differences in suction levels.i
Cycles per Second	Stimulation: 1.66– 2.0 Expression: 0.7-1.44	Stimulation: 1.66– 2.0 Expression: 0.8-1.44	Different; there are minor differences in cycle speeds.
Maximum vacuum	250 mmHg	250 mmHg	Identical
Suction setting	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 0-60rpm, 9 levels for speed. 9 levels for location on the breast (distance from the breast center)	4 cams rotating at a typical angular speed of 0-60rpm, 9 levels for speed. 9 levels for location on the breast (distance from the breast center)	Identical
Cycling Control Mechanism	Microcontroller	Microcontroller	Identical
Back Flow Protection	Yes	Yes	Identical
2-phase expression	Yes	Yes	Identical

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, with minor differences in the pumping options, cycle speeds, and vacuum strengths. 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.

- 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, " Content of Premarket Submissions for Device Software Functions," dated June, 2023.

Biocompatibility:

The materials of all parts that are in contact with the user remain the same for the Annabella Double Breast Pump as was tested for the Annabella Breast Pump, therefore, testing from the predicate device was leveraged to support the biocompatibility of the subject device.

Non-clinical Performance Testing:

- Vacuum level/suction strength of subject devices was tested for each mode/ cycle.
- 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

Double Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.