May 26, 2023

Guangzhou Yongyi Industrial Co., Ltd.
℅ Cassie Lee
Manager
Guangzhou GLOMED Biologcial Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 523000
China

Re: K223329
Trade/Device Name: Electric Breast Pumps (model: YY-A46, YY-A203, YY-A204, YY-TC201)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: April 24, 2023
Received: April 24, 2023

Dear Cassie Lee:

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,
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223329

Device Name
Electric Breast Pumps (model: YY-A46, YY-A203, YY-A204, YY-TC201)

Indications for Use *(Describe)*
The Electric Breast Pumps are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

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 – K223329

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter

Sponsor Name: Guangzhou Yongyi Industrial Co., Ltd.
Address: No. 4, Majun Rd., Dongchong Town, Nansha District, Guangzhou, Guangdong, China
Contact Person: Wei Hu
Establishment Registration Number: 3016562061
Tel: +86-020-39953345
Fax: +86-020-39953354
E-mail: diky@kidrobaby.com

Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Date of the summary prepared: May 25, 2023

3. Subject Device Information

Device/Trade Name: Electric Breast Pumps (Models: YY-A46, YY-A203, YY-A204, YY-TC201)
Common or Usual Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX (Pump, Breast, Powered)

4. Predicate Device

CIMILRE F1 and CIMILRE S3, K162870
This predicate device has not been subject to a design-related recall.

5. Device Description

The subject devices are intended to be used by lactating women to express and collect milk from their breasts. The devices are intended for a single user in the home environment or hospital setting. When properly connected, the pumping kit transfers the vacuum generated by the powered pump to the breast, enabling expression and collection of milk. A diaphragm in the backflow protection assembly physically isolates pump and tubing from the space where milk is expressed and collected, protecting the breast milk from contamination.

The Electric Breast Pumps contain 4 models, YY-A46, YY-A203, YY-A204 and YY-TC201. The YY-A46 model operates in single pumping mode only; models YY-A203, YY-A204 and YY-TC201 can be operated in single or double pumping modes. Models YY-A203 and YY-A204 have an LED panel and model YY-TC201 has an LCD panel to display working mode, cycle, timer, battery level, and Bluetooth symbol to user. While YY-A46 has an LED indicator to indicate the working status of the device, models YY-A46, YY-A203, and YY-A204 can be wirelessly operated via Bluetooth connection to a smart device. Users can select the working mode, adjust the suction level and cycle speed, and start or pause the device from a smart device. Model YY-TC201 can only be operated on the pump unit itself. All models have massage and expression mode and have a maximum working time of 30 minutes.

6. Indications for Use

The Electric Breast Pumps are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

7. 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.

Elements of Comparison	Subject Device	Predicate Device	Comparison
Sponsor	Guangzhou Yongyi Industrial Co., Ltd.	Cimilre Co., Ltd.	--
Device Name and Model	Electric Breast Pump, Models: YY-A46, YY-A203, YY-A204, YY-TC201	CIMILRE F1 and CIMILRE S3	--
510(k) Number	K223329	K162870	--
Product Code	HGX	HGX	Same
Device Class	II	II	Same
Indications for Use	The Electric Breast Pumps are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The CIMILRE F1 and CIMILRE S3 are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
Intended use population	Single user	Single user	Same
Intended use environment	Home environment	Home environment	Same
Power Supply	AC adapter: Input 100-240 VAC, 50/60Hz and output of 5V 1A DC Battery: YY-A46: 3.7V, 760mAh YY-A203, YY-A204, YY-TC201: 3.7V, 3000mAh	AC/DC Converter (12 VDC) Rechargeable Lithium Polymer Battery (only for CIMILRE F1)	Similar
Pump type	Diaphragm	Diaphragm	Same
Pump options	YY-A46: single YY-A203, YY-A204, YY-TC201: single or double	Single or double	Same
Black flow protection	Yes	Yes	Same
Modes	2 modes (massage mode, expression mode)	2 modes (massage mode, expression mode)	Same
Vacuum levels	YY-A46 Massage model: 6 levels Expression mode: 12 levels YY-A203, YY-A204, YY-TC201: Massage model: 5 levels Expression mode: 12 levels	CIMILRE F1 Massage model: 5 levels Expression mode: 10 levels CIMILRE S3 Massage model: 5 levels Expression mode: 12 levels	Similar
Suction Strength	YY-A46: Massage model: 60-185mmHg Expression mode: 45-260mmHg YY-A203, YY-A204, YY-TC201: Massage model: 65-200mmHg Expression mode: 75-265mmHg	40-280mmHg	Similar
Cycle range (Cycles/min)	Massage mode: YY-A46: 59/65/72/78/85/92 YY-A203, YY-A204: 50 YY-TC201: 45/50 Expression mode: YY-A46: 38/46/53/58/64/68/72 YY-A203, YY-A204, YY-	25-60 (F1) 30-60 (S3)	Similar

Elements of Comparison	Subject Device	Predicate Device	Comparison
	TC201: 20/24/28/32		
User interface/control	YY-A46: power button, mode button, suction increase, suction decrease, mode switch, indicator YY-A203, YY-A204: power button, nightlight button, expression mode, massage mode, suction increase, suction decrease, cycle up, cycle down, LCD Display YY-TC201: power button, suction increase, suction decrease, mode button, night light, LCD Display	Tact switch control Power, Vacuum/Cycle Up or Down; Mode switch LCD Display	Similar
Mobile application and wireless functionality	YY-A46, YY-A203, YY-A204: Bluetooth connectivity YY-TC201: None	None	Different

The subject and predicate device have similar indications for use statements and have the same intended use (i.e., to express and collect milk from the breasts of lactating women). The subject and predicate device have different technological characteristics, including different power supplies, vacuum strengths, cycle speeds, and user interfaces. However, these differences in technological characteristics do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject devices met all design specifications and that the subject devices are substantially equivalent to the predicate device. The subject devices were tested as follows:

1) Electromagnetic Compatibility and Electrical Safety

- ANSI AAMI ES 60601-1:2005/(R)2012 & A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)* [Including Amendment 2 (2021)] (Recognition Number 19-46)
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical equipment and medical electrical systems used in the home healthcare environment* (Recognition Number 19-38)

- IEC 60601-1-2 Edition 4.1 2020-09, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

2) Software Validation

The software documentation of the subject device was provided in accordance with FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005.

3) Biocompatibility

The pumping kits of the subject devices are identical to K192640 in formulation, processing, and cleaning. Therefore, biocompatibility information from K192640 can be leveraged to support the biocompatibility of patient-contacting components of the subject device.

4) Performance Testing

- Vacuum and cycle performance testing were conducted at all settings and demonstrated that the device met its specifications.
- Backflow protection testing was conducted to demonstrate that liquid does not backflow into the tubing/pump.
- Use life testing was conducted to demonstrate that the device maintains its performance specification 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.

9. Conclusion

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