March 30, 2020

Guangzhou Yongyi Industrial Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, 510000
CHINA

Re: K192640
Trade/Device Name: Kidro Digital Electric Breast Pump, Dr. Brown's Digital Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 25, 2020
Received: February 28, 2020

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,

For
Monica D. Garcia, Ph.D.
Acting 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)*
K192640

Device Name
Kidro Digital Electric Breast Pump, Dr. Brown's Digital Electric Breast Pump

Indications for Use *(Describe)*
The Kidro Digital Electric Breast Pump and Dr. Brown's Digital Electric Breast Pump are powered breast pumps to be used by lactating women to express and collect milk from their breasts. They are 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
K192640

1. Submitter Information

Sponsor Name: Guangzhou Yongyi Industrial Co., Ltd.
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Contact name: Jian Zhongrong (GM)
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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

Date summary was prepared: March 25, 2020

2. Subject Device Information

Trade Name: Kidro Digital Electric Breast Pump, Dr. Brown's Digital Electric Breast Pump
Models: Kidro: YY-A11, YY-A21, YY-A31, YY-A41, YY-A51, YY-A103, YY-A104
Dr. Brown's: BF103, BF100
Common Name: Powered Breast Pump
Regulation Number: 884.5160
Product Code: HGX (pump, breast, powered)
Class: II
Review Panel: Obstetrics/Gynecology

3. Predicate Device Information

510(K) Number: K181937
Device Name: Pump In Style® Advanced
Manufacturer: Medela LLC

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

4. Device Description

The Kidro Digital Electric Breast Pump and Dr. Brown's Digital Electric Breast Pump are single-user powered breast pumps capable of single pumping or double pumping. The subject devices are powered by a rechargeable lithium ion battery or AC adapter. They are non-sterile. The powered breast pumps' drive unit employs a diaphragm-type vacuum pump, powered by a DC-motor, supervised by a microcontroller. The microcontroller provides control over vacuum pressure and cycle speed.

Models YY-A11, YY-A21 and YY-A41 are capable of single pumping and have two modes:

- Massage mode: Helps to relax the muscle around the breast and prepare for suction.
- Normal mode: Suction patterns are characterized by low vacuum to start milk flow.

In addition to the two modes described above, Models YY-A31, YY-A51, YY-A103, YY-A104, and BF103 are capable of single pumping and have an additional mode:

- Rapid mode: Suction patterns are characterized by high vacuum to express more milk.

Model BF100 is capable of single and double pumping and has two modes only:

- Letdown mode: Helps to relax the muscle around the breast and prepare for suction.
- Expression mode: Suction patterns are characterized by high vacuum to express more milk.

5. Indications for Use

The Kidro Digital Electric Breast Pump and Dr. Brown's Digital Electric Breast Pump are powered breast pumps to be used by lactating women to express and collect milk from their breasts. They are intended for a single user.

6. Predicate Comparison

The following table compares the subject devices to the predicate with respect to the indications for use and technological characteristics:

Device	**Subject Device K192640**	**Predicate Device K181937**
Company	Guangzhou Yongyi Industrial Co., Ltd.	Medela LLC
Name and Model	Kidro Digital Electric Breast Pump Models: YY-A11, YY-A21, YY-A31, YY-A41, YY-A51, YY-A103, YY-A104 Dr. Brown's Digital Electric Breast Pump Models: BF103, BF100	Pump In Style® Advanced
510(k) Number	K192640	K181937
Patient Population	Lactating women	Lactating women
Indications for Use	The Kidro Digital Electric Breast Pump and Dr. Brown's Digital Electric Breast Pump are powered breast pumps to be used by lactating women to express and collect milk from their breasts. They are intended for a single user.	The Pump In Style® Advanced breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The powered breast pump is intended for a single user.
Environment of Use	Home	Home
Single/double pump	Single: YY-A11, YY-A21, YY-A31, YY-A41, YY-A51, YY-A103, YY- A104, BF103 Double: BF100	Single and double pumping
Direct user contact	Yes	Yes
Adjustable pumping levels	Yes	Yes
Visual indicator	LED: YY-A11, YY-A21, YY-A41 LCD Screen: YY-A31, YY-A51, YY- A103, YY-A104, BF103, BF100	No visual indicator
Maximum vacuum (mmHg)	-295 mmHg	-295 mmHg

Vacuum range (mmHg)	YY-A11/YY-A21/YY-A41: -67.5 to -285mmHg YY-A31/YY-A51/YY-A103/YY-A104/BF103: -97.5 to -295mmHg BF100: -45 to -231mmHg	-50 to -240 mmHg
Cycle Speed	YY-A11/YYA21/YY-A41: 49-63 cycles/min YY-A31/YY-A51/YY-A103/YY-A104/BF103: 40-63 cycles/min BF100: 36-63 cycles/min	120 cycles
Cycling/Suction Control	Microprocessor	Microprocessor
Power Supply type	AC Adapter or rechargeable lithium battery	AC Adapter, AA batteries, or Switching vehicle power adapter
Battery use life	Approx.1.5h for pumping time	Unknown
Low battery indicator	Yes	Unknown
Automatic Power Off	Yes	Unknown

The subject devices have similar indications for use and the same intended use as the predicate device, As noted in the table above, the subject and predicate devices have different technological characteristics. The differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Testing

Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

a. Electromagnetic Compatibility, Electrical Safety, and Battery Safety: The subject devices were tested in compliance with the following:
   i. ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   ii. IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
   iii. IEC 60601-1-11 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
   iv. IEC 62133-2 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

b. Biocompatibility: Patient contacting components were subjected to biocompatibility testing in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation

and testing within a risk management process, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10).

c. Software Verification: Software documentation 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.

d. Performance Testing: Bench testing was conducted to demonstrate pump performance (vacuum performance, speed verification, milk collection in the worst-case scenario), battery performance, backflow protection, and overflow protection were tested using internal test protocols.

8. Conclusion

The results of the performance testing described above demonstrate that the Kidro Digital Electric Breast Pump and Dr. Brown's Digital Electric Breast Pump are as safe and effective as the predicate device and supports a determination of substantial equivalence.