



March 13, 2024

Hygeia II Medical Group, Inc.
Brett Nakfoor
CEO
6241 Yarrow Drive, Suite A
Carlsbad, California 92011

Re: K233136
Trade/Device Name: Hygeia Express Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 25, 2023
Received: September 27, 2023

Dear Brett Nakfoor:

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)
K233136

Device Name
Hygeia Express Powered Breast Pump

Indications for Use (Describe)

The Hygeia Express Powered Breast Pump is a powered breast pump intended to express and collect milk from the breasts of a lactating woman. It is intended for a single user only.

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 – K233136

1. Submitter Information

Applicant: Hygeia II Medical Group, Inc.
Phone: (714) 515-7571
Address: 6241 Yarrow Drive Suite A Carlsbad CA
92011 United States

2. Correspondent Information

Contact: Brett Nakfoor,
CEO,
Email: bnakfoor@hygeiahealth.com
Phone: (714) 515-7571

3. Date prepared: March 11, 2024

4. Device Information

Device Name: Hygeia Express Powered Breast Pump
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: Electric Breast Pump
510(k) Number: K211024
Manufacturer: Shantou Huihengqi Electronic Technology Co., Ltd.

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

6. Device Description

The Hygeia Express Powered Breast Pump is an electrically powered breast pump to be used in a home environment by a single user. The device is provided non-sterile and can be used on one breast (single pumping) or on both breasts at the same time (double pumping).

The device consists of a pump, Personal Accessory Set (PAS) pumping kit, and an AC adapter. The pump is also configurable with a wearable PAS kit which allows milk to flow into a cup pressed against the breast during use. It does not incorporate off-the-shelf (OTS) software or wireless technology/mobile app software functionality. The Hygeia Express Powered Breast Pump has a backlit LCD display, which shows pumping mode, suction level, timer, and battery level. The device also has four buttons allowing the user to power the device on/off, select between three pumping modes (massage, expression, and stimulation), and control vacuum strength within each mode (9 levels of vacuum strength in each mode). 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 ± 25 mmHg in at speeds between 20 and 150 ± 5 cycles per minute. There are 3 available pumping modes with 9 distinct levels of vacuum and cycle speed.

When connected to the pump, the PAS 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.

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 Hygeia Express Powered Breast Pump is a powered breast pump intended to express and collect milk from the breasts of a lactating woman. It is intended for a single user only.

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

| | Hygeia Express Powered Breast Pump K233136 Subject Device | Electric Breast Pump K211024 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 Hygeia Express Powered Breast Pump is a powered breast pump intended to express and collect milk from the breasts of a lactating woman. It is intended for a single user only. | The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user. | Same |
| Single/double pump | Single or double | Single or double | Same |
| Media separation (backflow protection) | Yes | Yes | Same |
| Cycling control mechanism | Microcontroller | Microcontroller | Same |
| Expression pattern | 2-Phase | 2-Phase | Same |
| Power supply | Li-Ion Battery or mains | Li-Ion Battery or mains | Same |
| Suction levels (massage) | $50-170 \pm 25$ mmHg | Two in one: $75-285 \pm 20$ mmHg | Different |

| | | | |
|--|---|---|------------------|
| | | Dual frequency: 67.5-277.5 ± 20 mmHg | |
| Suction levels (expression) | 70-250 ± 25 mmHg | 105-285 ± 20 mmHg | Different |
| Suction levels (stimulation) | 70-250 ± 25 mmHg | 60-217.5 ± 20 mmHg | Different |
| Cycles per minute (massage) | 70-150 ± 5 cpm | Two in one: 59-123 ± 20 mmHg Dual frequency: 39-85 ± 20 mmHg | Different |
| Cycles per minute (expression) | 36-136 ± 5 cpm | 24-84 ± 5 cpm | Different |
| Cycles per minute (stimulation) | 20-33 ± 5 cpm | 39-123 ± 5 cpm | Different |
| Suction levels | 9 massage, 9 expression, 9 stimulation | 5 stimulation, 7 expression, 7 two in one, 7 dual frequency, 1 stimulation | Different |
| User Interface | On-Off switch, mode change button, vacuum adjustment buttons, LCD (mode, time, vacuum level, battery) | On-Off switch, mode change button, vacuum adjustment buttons, LCD (mode, time, vacuum level, battery) | Similar |
| Adjustable Suction Levels | Yes | Yes | Same |
| Mobile Application | No | No | Same |
| Design | Tabletop or wearable | Tabletop or wearable | Same |

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 tabletop/wearable operation, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum/cycle specifications and available suction levels in each mode. 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 information was provided in accordance with Attachment G of the 2023 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."*

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 at the Basic Documentation level as recommended in the 2023 FDA guidance document “*Content of Premarket Submissions for Device Software Functions.*”

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