October 18, 2019

Hygeia II Medical Group, Inc.
Brett Nakfoor
CEO
6241 Yarrow Drive
Carlsbad, CA 92011

Re: K190465
Trade/Device Name: Evolve Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 18, 2019
Received: September 20, 2019

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 (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.


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,

Sharon M. Andrews -S

Sharon Andrews
Acting 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

Device Name
Evolve breast pump

Indications for Use (Describe)
The Evolve breast pump is intended to be used by lactating women to express and collect milk from their breasts.

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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In accordance to CFR Title 21, Sec. 807.92 the following summary is provided.

SUBMITTER:

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DATE PREPARED: October 16, 2019

Device Information

Trade Name: Evolve Breast Pump
Common Name: Powered Breast Pump
Classification Name: Powered Breast Pump
Classification Panel: Obstetrics/Gynecology
Regulation: 21 CFR 884.5160
Device Classification: Class II
Product Code: HGX
Product Code Name: Pump, Breast, Powered

Predicate Device Information

Hygeia EnDeare Breast Pump, K081932
This predicate has not been subject to a design-related recall.
**Device Description**

The Evolve Breast Pump, is an electrically powered breast pump from an external AC-DC power supply; the device is provided non-sterile.

The Evolve Breast Pump is intended to be used by lactating women to express and collect milk from their breasts. Pumping can be performed on one breast (single pumping) or on both breasts of a lactating woman at the same time (double pumping). The Evolve breast pump is designed as a multi-user breast pump and available in a corded model (external AC-DC power supply).

The Evolve Breast Pump utilizes a DC-powered motor driving a reciprocating-type vacuum pump and an electromechanical solenoid which are controlled electronically to provide vacuum (suction) capability that extracts and collects milk from breasts of lactating women.

The Evolve Breast Pump has a backlit, LCD display for user display. The subject device also has soft-touch buttons for the user to power the device on/off, switch between two different pumping modes - stimulation and expression – and to control vacuum speed and strength within each of the modes. Multiple vacuum speed and strength settings are available in both pumping modes.

The Evolve Breast Pump is intended for repeated use by multiple users in home environment.

The Evolve Breast Pump requires Hygeia’s Personal Accessory System for users to express and collect milk from their breasts.

**Indications for Use**

The Evolve breast pump is intended to be used by lactating women to express and collect milk from their breasts.
Comparison of Technological Characteristics

The Evolve Breast Pump has identical indications for use and uses the same fundamental technology as the legally marketed predicated devices to which substantial equivalency is claimed, EnDeare Breast Pump (K081932). The modifications that are subject to this submission include the device’s form-factor, user interface, vacuum source - performance specification, and firmware:

a) Form-factor/dimension - physical size of subject device is smaller and has a different shape than the predicate in order to improve aesthetics

b) User interface - to improve aesthetics, the subject device has an LCD user display versus predicate device’s printed indicators and subject device has button controls versus rotary knob controls on predicate device

c) Vacuum source/performance - The subject device provides negative pressure vacuum (suction) through a DC-powered, reciprocating-based pump and an electromechanical vacuum release solenoid where vacuum speed and strength are controlled electronically. The predicate device provides negative pressure vacuum through a DC-powered, reciprocating-based pump with a mechanical vacuum release design. Thus, subject device has vacuum speed and strength controlled electronically while predicate has vacuum speed controlled electronically and vacuum strength controlled mechanically (by user).

d) Firmware - The embedded logic of the subject device has been changed to handle modifications listed above; user interface changes, control and management of reciprocating pump and electromechanical solenoid

e) Backflow protection - backflow protection mechanism changed from hydrophobic filter to diaphragm

A summary of the technological characteristics compared to the legally marketed predicate device (K081932) are shown in the following table.
## Indications for Use

- **Evolve K190465**: The Evolve powered breast pump is to be used by lactating women to express and collect milk from their breasts.
- **EnDeare (Predicate Version) K081932**: The EnDeare powered breast pump is indicated to express and collect milk from the breasts of lactating women.

## Environment of Use

- **Evolve K190465**: Home
- **EnDeare (Predicate Version) K081932**: Hospital, Home

Subject device marketed for home use.

## User Interface - Controls

### User Control
- **Evolve K190465**
  - State-dependent controls: On-Off button
  - Stimulation and Expression Mode button
  - Performance controls: Strength and Speed adjustment via buttons
- **EnDeare (Predicate Version) K081932**
  - State-dependent controls: On-Off switch
  - No Mode button
  - Performance controls: Speed and Strength adjustment via rotary knob and pressure collar

Subject device supports 2 pumping modes: Stimulation & Expression, predicate has 1 mode.

### Visual Indicator
- **Evolve K190465**: LCD Backlit, liquid-crystal display
- **EnDeare (Predicate Version) K081932**: Printed graphics on pump case

Addition of LCD display.

### Pumping Options
- **Evolve K190465**: Single pumping
  - Double pumping
- **EnDeare (Predicate Version) K081932**: Single pumping
  - Double pumping

Same.

### Adjustable Suction Level
- **Evolve K190465**: Yes
- **EnDeare (Predicate Version) K081932**: Yes

Same.

### Adjustable Speed Level
- **Evolve K190465**: Yes
- **EnDeare (Predicate Version) K081932**: Yes

Same.

### Accessories
- **Evolve K190465**: Personal Accessory Set:
  - Breast shield
  - Diaphragm
  - Valve
  - Tubing
  - Bottles
  - AC-DC power-adapter-cord
- **EnDeare (Predicate Version) K081932**: Personal Accessory Set:
  - Breast shield
  - Filter
  - Valves
  - Tubing
  - Bottles
  - AC power cord, rechargeable battery

Hygeia Personal Accessory Set.

### Cleaning
- **Evolve K190465**: Breast pump - wipe with clean, damp cloth
  - Tubing - replace if milk appears in tubing
  - Breast pump kit and bottles – wash and sanitize
- **EnDeare (Predicate Version) K081932**: Breast pump - wipe with clean, damp cloth
  - Tubing - wash or sanitize only if milk or condensation in tubing
  - Breast pump kit and bottles – wash and sanitize

Same except tubing shall be replaced for subject device if milk appears in tubing.

### Specifications
The differences in technological characteristics do not raise different questions of safety and effectiveness.
Summary of Performance Data, Non-Clinical Testing

The Evolve Breast Pump complies with voluntary standards for electrical safety, electromagnetic compatibility, and use in the home environment.

The following performance data is provided in support of the substantial equivalence determination:

Risk/Hazard
- Risk Analysis in accordance with ISO 14971:2007 was used to assess impact of modifications to the device

Electrical Safety and Electromagnetic Compatibility (EMC)

Firmware Testing
- The software/firmware verification and validation was provided in accordance with the FDA Guidance document, "The Content of Premarket Submissions for Software Contained in Medical Devices," issued on May 11, 2005
Performance Testing
The Evolve Breast Pump was tested to demonstrate it meets its performance specifications. The testing involved measurement of vacuum and cycles for minimum and maximum settings for both single and double pumping mode, and for stimulation and expression mode. Also, backflow protection was tested. Specifications were met and within required, acceptable range for pump operation, cycle rate, and vacuum pressure.

Conclusion
The performance testing demonstrates that the Evolve Breast Pump is substantially equivalent to the predicate device.