March 18, 2020

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

Re: K200406
Trade/Device Name: Evolve Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 18, 2020
Received: February 19, 2020

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.

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
Sharon M. Andrews
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)*
K200406

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY – K200406

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

SUBMITTER:

Hygeia II Medical Group, Inc.
6214 Yarrow Drive, Suite A
Carlsbad, CA 92011
Phone: (714) 515-7571

PRIMARY CONTACT PERSON:

Brett Nakfoor
CEO
Hygeia II Medical Group
(714) 515-7571

SECONDARY CONTACT PERSON:

John Conklin
Product Development
Hygeia II Medical Group
(714) 515-7571

DATE PREPARED: March 12, 2020

Device Information

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

Predicate Device Information

Hygeia Evolve Breast Pump, **K190465,** October 18, 2019.

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

Device Description

The Evolve Breast Pump, the subject device, is an electrically powered breast pump from an external AC-DC power supply or internal, rechargeable batteries; the device is provided non-sterile. The subject device is a cordless version of the predicate device.

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 breast pump is designed as a multi-user breast pump and is available as a cordless model powered by an internal, rechargeable Lithium Ion battery or an 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. 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 the 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 the same fundamental technology as the legally marketed predicated device, the Evolve Breast Pump (K190465). The modification to the predicate device, subject to this submission, is the addition of an internal rechargeable Lithium Ion battery to allow cordless operation of the breast pump.

A summary of the technological characteristics of the subject and predicate device are shown in the following table.

	Evolve **K200406**	**Evolve** ***(Predicate Version)*** ***K190465***	**Comment**
Indications for Use	The Evolve powered breast pump is to be used by lactating women to express and collect milk from their breasts.	The Evolve powered breast pump is to be used by lactating women to express and collect milk from their breasts.	Same

Environment of Use	Home	Home	Same
User Interface - Controls			
User Control	State-dependent controls: On-Off button Stimulation and Expression Mode button Performance controls: Strength and Speed adjustment via buttons	State-dependent controls: On-Off button Stimulation and Expression Mode button Performance controls: Strength and Speed adjustment via buttons	Same
Visual Indicator	LCD Backlit, liquid-crystal display	LCD Backlit, liquid-crystal display	Same
Pumping Options	Single pumping Double pumping	Single pumping Double pumping	Same
Adjustable Suction Level	Yes	Yes	Same
Adjustable Speed Level	Yes	Yes	Same
Accessories	Personal Accessory Set: • breast shield • diaphragm • valve • tubing • bottles AC-DC power-adapter-cord	Personal Accessory Set: • breast shield • diaphragm • valve • tubing • bottles AC-DC power-adapter-cord	Same All components and accessories have been cleared with predicate device (K190465)
Cleaning	Breast pump - wipe with clean, damp cloth Tubing - replace if milk appears in tubing Breast pump kit and bottles – wash and sanitize	Breast pump - wipe with clean, damp cloth Tubing - replace if milk appears in tubing Breast pump kit and bottles – wash and sanitize	Same
Specifications			
Power Source	AC-DC 100 - 240 Vac adapter, 50/60 Hz	AC-DC 100 - 240 Vac adapter, 50/60 Hz	Same
Batteries	Internal, rechargeable Lithium Ion battery	N/A	Subject device has internal Lithium Ion battery
Rechargeable Battery operation/charge time	Operation time: Approximately 120 Minutes Charge time: Approximately 180 Minutes	N/A	Subject device provides ability to operate in cordless configuration by battery
Software/firmware	Yes	Yes	Same
Vacuum aggregate type	Reciprocating pump	Reciprocating pump	Same

Vacuum Regulation type	Electronic	Electronic	Same
Maximum vacuum (mmHg)	-283 mmHg (-20 mmHg)	-283 mmHg (-20 mmHg)	Same
Vacuum range – double and single pumping (mmHg)	**Stimulation** -75 to -175 mmHg (±20 mmHg) **Expression** -140 to -283 mmHg (±20 mmHg)	**Stimulation** -75 to -175 mmHg (±20 mmHg) **Expression** -140 to -283 mmHg (±20 mmHg)	Same
Cycling Control Mechanism	Electronic	Electronic	Same
Cycle Speed Range (Cycles/Minute = CPM)	**Stimulation** 75 to 92 CPM (±8 CPM) **Expression** 32 to 49 CPM (±8 CPM)	**Stimulation** 75 to 92 CPM (±8 CPM) **Expression** 32 to 49 CPM (±8 CPM)	Same
Adjustable Cycle Speed Levels	Yes	Yes	Same
Backflow protection	Yes, silicone diaphragm	Yes, silicone diaphragm	Same

The differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Performance Data

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)

- Electrical safety testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 standard
- Electromagnetic compatibility testing per IEC 60601-1-2: 2014 (4th edition) standard, Medical Electrical Equipment Part 1 - 2

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

with the internal, rechargeable Lithium Ion battery to show battery energy capacity is sufficient to assure the subject device performs to its specifications. Specifications were met and are within the required, acceptable ranges for pump operation, cycle rate, vacuum pressure, and battery operation time.

Conclusion

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