March 15, 2022

Hygeia II Medical Group, Inc.
John Conklin
VP Product Development
6241 Yarrow Drive
Carlsbad, CA 92011

Re: K212955
Trade/Device Name: FIT Pro Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 14, 2022
Received: February 15, 2022

Dear John Conklin:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K212955

Device Name

FIT Pro Breast Pump

Indications for Use *(Describe)*

The FIT Pro Breast Pump is a single-user, powered breast pump 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.

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

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510(K) SUMMARY
K212955

In accordance with 21 CFR 807.92(a) the following summary is provided:

DATE PREPARED: March 14, 2022

SUBMITTER:

Hygeia II Medical Group, Inc.
6241 Yarrow Drive
Carlsbad, CA 92011
Phone: 714-615-7571

PRIMARY CONTACT PERSON:

Brett Nakfoor
CEO
Hygeia II Medical Group, Inc.
847-964-2620

Device information

Trade Name: FIT Pro Breast Pump
Common Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Product Code: HGX (Pump, Breast, Powered)
Classification Panel: Obstetrics/Gynecology
Regulatory Class: II

Predicate Device Information

Ameda Mya Joy PLUS: **K203570**

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

Reference Device Information

Evolve Breast Pump: K190465

Device Description

The FIT Pro Breast Pump is an electric breast pump powered by an external AC-DC power supply or by an internal rechargeable lithium-ion battery. The device is provided non-sterile.

The device is intended to be used by lactating women to express and collect milk from their breasts. Pumping can be performed on either one breast (single pumping) or both breasts at the same time (double pumping).

The FIT Pro Breast Pump utilizes a DC-powered motor driving a diaphragm-type vacuum pump and an electromechanical solenoid which are controlled electronically to provide a range of user-selectable vacuum (suction) levels at various pre-determined cycle frequencies.

The FIT Pro Breast Pump has a backlit LCD display, which shows pumping mode, suction level, timer, and battery level. The device also has four soft-touch buttons allowing the user to power the device on/off, switch between stimulation and expression pumping modes, and control vacuum strength within each mode (6 levels of vacuum strength in stimulation mode and 12 levels in expression mode).

The FIT Pro Breast Pump is intended for a single user in the home environment. When properly connected, the Hygeia 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.

The base model of the FIT Pro Breast Pump contains a pump, pumping kit, AC adapter with detachable USB-C cable, and a lanyard.

Indications for Use

The FIT Pro Breast Pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

The intended use and key technological characteristics of the FIT Pro Breast Pump and thepredicate device are compared side-by-side in the table below.

	Proposed Device	***Predicate Device***
Device name	FIT Pro Breast Pump	Mya Joy PLUS
510(k) Number	K212955	K203570
Manufacturer	Hygeia II Medical Group, Inc.	Ameda, Inc.
Product Code	HGX	HGX
Device Class	2	2
Indications for Use	The FIT Pro Breast Pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.	The Ameda Mya Joy PLUS breast pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.
Intended Use Environment	Home Environment	Home Environment
POWER		
Power Source (external)	AC/DC adapter; 5VDC	AC/DC adapter; 5VDC
Power Source (internal)	rechargeable lithium-ion battery 3.7 V, 1500 mAh	rechargeable lithium-ion battery 3.7 V, 1500 mAh
Battery performance	At least 2 hours on full charge	At least 2 hours on full charge
Auto Power-off	After 45 minutes in expression mode	After 45 minutes in expression mode
VACUUM PERFORMANCE		
Pump Type	Diaphragm	Diaphragm
Pump Options	Single or Double	Single or Double
Modes	Stimulation and Expression	Stimulation and Expression

	Proposed Device	***Predicate Device***
Vacuum levels	6 (stimulation) 12 (expression)	6 (stimulation) 12 (expression)
Vacuum range	40 – 270 mm Hg	40 – 250 mm Hg
Cycle range	80 – 120 cycles/minute (stimulation) 25 – 63 cycles/minute (expression)	80 – 120 cycles/minute (stimulation) 25 – 63 cycles/minute (expression)
Cycle speed	Pre-programmed	Pre-programmed
USER INTERFACE		
LCD Display	Mode, Time, Vacuum Level, Battery	Mode, Time, Vacuum Level, Battery
Button controls	Power, Mode, Increase, Decrease	Power, Mode, Increase, Decrease
Pumping Kit		
Backflow Protection	Circular silicone diaphragm	Cylindrical silicone diaphragm
Flange Design	Multi-piece	Single Piece
Flange and Bottle Material	Polypropylene	Polypropylene
Valve Design	Duckbill	Duckbill
Valve Material	Silicone	Silicone
Single-pumping plug shape	Truncated Cylindrical	Cylindrical

The subject and predicate device have similar indications for use statement and have the same intended use – to express and collect milk from lactating women. The subject and predicate devices are based on the same vacuum pump platform. The designs, both hardware and software, are identical. Both devices utilize identical lithium-ion batteries of equal capacity.The time before automated shut-off is identical in either device. While both subject and predicate devices share a vacuum range from 40 to 250 mm Hg, the subject device is capable of 270 mm Hg maximum vacuum in expression mode while double pumping. The pumping speeds for both the subject and predicate devices are identical at equivalent settings in either mode.

The subject device has identical patient contacting materials when compared to the reference device, K190465.

The principal differences in technological characteristics between the subject device and the predicate are limited to differences in the pumping kit. Similarities include shape of the breast shield, size and shape of the milk bottle, and valve material and design. Key differences are backflow protector shape, multi-piece (versus integrated) connector and the design of the plug that allows single pumping. Functionally similar kit parts are made of the same type of material, either polypropylene or silicone.

In the subject device, tubing points away from the user, while tubing in the predicate device rises vertically from the flange assembly. This difference in design does not affect pump performance and does not raise different questions of safety and effectiveness as compared to the predicate device.

The circular diaphragm of the subject device flexes under vacuum in a manner different from the cylindrical diaphragm of the predicate. The multi-piece connector assembly has more connecting surfaces than the predicate, which presents more areas of potential air leaks. The difference in plug shape for single pumping provides a controlled air leak, resulting in a slightly lower vacuum at any setting. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

Summary Of Non-Clinical Testing

The FIT Pro Breast Pump complies with the following recognized voluntary standards for risk management, electrical safety, electromagnetic compatibility, and use in the home healthcare environment.

The data below were provided in support of the substantial equivalence determination.

Risk Analysis in accordance with ISO 14971:2007

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

Use in the home healthcare environment per IEC 60601-1-11:2010

Software verification and validation was conducted in accordance with the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" to support a moderate level of concern.

Non-clinical Performance Testing

The FIT Pro Breast Pump was tested to demonstrate it meets stated performance specifications.

Testing involved measurement of vacuum and cycle speed at user-selectable settings in both stimulation and expression modes for pumping at a single breast (single pumping) and both breasts simultaneously(double pumping). Testing was conducted separately under two states of power: (1) externally supplied by an AC/DC adapter and (2) internally supplied from a rechargeable lithium-ion battery. Specifications were met under all conditions.

Testing confirmed device life and battery operating time, battery indicator accuracy, and verified protection against backflow and overflow.

The test results for the non-clinical testing outlined above demonstrated that the FIT Pro Breast Pump met the predetermined acceptance criteria.

Conclusion

The results of the performance testing described above demonstrate that the Fit Pro Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.