October 19, 2021

Uzinmedicare Co.
% Adrienne Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps, & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005

Re: K210124
Trade/Device Name: Synergy Gold (SG) Portable (Models MM011450 and MM011460)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 20, 2021
Received: September 21, 2021

Dear Adrienne Lenz:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210124

Device Name
Synergy Gold (SG) Portable (Models MM011450 and MM011460)

Indications for Use *(Describe)*
The Synergy Gold (SG) Portable (Models MM011450 and MM011460) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Synergy Gold (SG) Portable (Models MM011450 and MM011460) breast pump is intended for home use by 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

K210124

DATE: October 18, 2021

SUBMITTER:

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DEVICE:

TRADE NAME: Synergy Gold (SG) Portable (Models MM011450 and MM011460)
COMMON/USUAL 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
REVIEW PANEL: Obstetrics/Gynecology

PREDICATE DEVICE(S):

K191208 Spectra Cashmere Breast Pump

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

The Medela Pump In Style (K200508) was used as a reference device.

DEVICE DESCRIPTION:

The Synergy Gold (SG) Portable is a powered breast pump intended to express and collect milk from the breasts of lactating women. Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time. The user employs buttons to select one or both sides for pumping, to switch from massage mode to expression mode and to control the vacuum levels within those modes. Massage mode consists of 5 suction levels, while expression mode has 12 suction levels. The SG Portable breast pump is capable of providing vacuum levels from 50-270 mmHg with cycling rate or 100 cycles per minute in massage mode and 26 cycles per minute in expression mode. The SG Portable breast pump is powered by a 5V DC adaptor or an internal rechargeable lithium-ion polymer battery.

The SG Portable breast pump is sold in two configurations (with and without breast shield and bottle sets). Model MM011450 includes the SG Portable breast pump, double collection kit (MM12302-C; breast shield set – medium 24 mm), power adapter, and two collection bottles. Model MM011460 includes the SG Portable breast pump and power adaptor; this model is to be used with separately purchased compatible breast shields and bottle sets.

The SG Portable breast pump and associated breast pump kits are intended for a single user.

INDICATIONS FOR USE:

The Synergy Gold (SG) Portable (Models MM011450 and MM011460) is a powered breast pump to be used by lactating women to express and collect milk from their breast.

The Synergy Gold (SG) Portable (Models MM011450 and MM011460) breast pump is intended for home use by a single user.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Synergy Gold (SG) Portable breast pump represents a modification to the legally marketed predicate device (Spectra Cashmere Breast Pump, K191208) to which substantial equivalence is claimed. All patient and breast milk contacting materials are identical between the subject and predicate devices.

The table below compares the intended use and technological characteristics of the subject and predicate device.

	Predicate Device **Spectra Cashmere Breast Pump (K191208)**	**Subject Device** **Synergy Gold Portable (K210124)**	**Comparison**
Patient Population	Breastfeeding women	Breastfeeding women	Same
Indications for Use	The Spectra Cashmere Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra Cashmere Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.	The Synergy Gold (SG) Portable (Models MM011450 and MM011460) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Synergy Gold (SG) Portable (Models MM011450 and MM011460) breast pump is intended for home use by a single user.	Same intended use
Environment of Use	Hospital, Home	Home	Different
User Control	Touch switches to control • vacuum setting left/right pump • right/left pump activation • cycle speed setting • mode of operation/mute • night light • power (on/off)	Touch switches to control • vacuum setting left/right pump • right/left pump activation • mode of operation/mute Button to control • power (on/off)	Different
Visual Indicator	LED display indicates • vacuum setting (each motor) • cycle speed setting • mode of operation • pump operating time • mute	LED display indicates • vacuum setting (each motor) • mode of operation • pump operating time • mute • battery status	Different

	Predicate Device Spectra Cashmere Breast Pump (K191208)	Subject Device Synergy Gold Portable (K210124)	Comparison
Night Light	LED light with two lighting levels	None	Different
Modes of Operation	Massage, Expression	Massage, Expression	Same
Single/Double Pumping	Single or Double	Single or Double	Same
Accessories	Breast shield set, power adapter, bottle set	Breast shield set, power adapter, bottle set	Same
Pump Type	Diaphragm	Diaphragm	Same
Suction Levels	15 Levels	12 Levels for expression 5 Levels for massage	Different
Suction Strength	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)	50 (±50) mmHg to 270 (-50 mmHg) (maximum 270 mmHg)	Same
Cycle Levels	5 levels for massage and 5 levels for expression	1 level for massage and 1 level for expression	Different
Cycle Speed	38-76 cycles/min (adjustable)	100 cycles/min for massage 26 cycles/min for expression	Different
Power Supply (Conventional Outlet)	AC/DC wall converter Input 100V – 240AC, 50/60Hz, 500mA Output : 12V, 2A	AC/DC wall converter Input 100 – 240V, 50/60Hz, 500mA Output : 5V, 2A	Different
Power Supply (Battery)	No battery	Li-ion polymer 7.4vdc 1700mAh	Different
Back Flow Protection	Yes, provided by silicone membrane backflow protector	Yes, provided by silicone membrane backflow protector	Same
Software	Yes	Yes	Same

The indications for use of the subject and predicate devices are not identical. Both the subject and predicate devices have the same intended use to express and collect milk from the breasts of a lactating woman and are for use by a single user in a home-use setting. The predicate device differs in that it can also be used in a hospital setting by multiple users. This difference does not represent a new intended use, but rather, a more limited use for the subject device.

The subject and predicate device have similar technological characteristics, including design, maximum vacuum level, modes of operation, back flow protection method, software control, and accessories. The different technological characteristics of the subject device, including visual indicators, user controls, number of vacuum and cycle levels, power adapter, battery operation, and lack of a night light function do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTS:

The SG Portable breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following performance data are provided in support of the substantial equivalence determination:

- Electrical Safety testing in accordance with the following standards:
  - ANSI/AAMI ES60601-1:2005+A1:2012
  - IEC 60601-1-11:2015
  - IEC 62133:2012
- Risk analysis in accordance with ISO 14971:2007 (Second Edition)
- Electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014
- Biocompatibility evaluation was not conducted on the patient-contacting materials of the device as all patient-contacting materials are identical to those used in the predicate device. Therefore, the biocompatibility information from the predicate device was used in support of the patient-contacting materials of the subject device.
- The software validation was provided in accordance with the FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005. The software for the subject device was considered as a "Moderate" level of concern, since prior to mitigations of hazards, failure of the software could lead to minor injury, such as pain.
- Bench testing was conducted to demonstrate that the device meets its performance specifications. The testing involved measurement of vacuum and cycles for both single and double pumping, AC and battery power, performance with all breast shield sizes, and verification of backflow protection.
- Battery and pump use-life testing was conducted to demonstrate that the device maintains its specifications throughout its use-life.

CONCLUSION:

The non-clinical testing demonstrates that the SG Portable breast pump is as safe and effective as the predicate device.