DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2016

Naya Health Inc.
% Paul Dryden
Consultant
390 Bridge Pkwy, Suite C
Redwood City, CA 94065

Re: K160511
Trade/Device Name: Naya Breast Pump System
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: May 20, 2016
Received: May 23, 2016

Dear Paul Dryden,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Form Approved: OMB No. 0910-0120

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K160511

Device Name

Naya Breast Pump System

Indications for Use *(Describe)*

The Naya Breast Pump System is a powered breast pump to be used by lactating women in the hospital or home setting 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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510(k) Summary

Date of Preparation: 21-Jun-16

Naya Health, Inc.
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Redwood City, CA 94065

Tel – 650-346-6271
Fax – 847-680-6269

Official Contact: Janica B. Alvarez – Co-founder and CEO

Proprietary or Trade Name: Naya Breast Pump System

Common/Usual Name: Powered breast pump

Classification Name: Powered breast pump
HGX - CFR 884.5760
Class II - OTC

Predicate Devices: K151632 – Medela – Symphony

Device Description:
The Naya Breast Pump System is a personal use electric breast pump capable of single or double pumping. The device is electrically powered from either an internal rechargeable battery or an external supply. The external supply also charges the battery. The device can also connect to an iPhone (iOS 8.0+) application (Mobile App) that replicates the front panel controls and indicators on the pump.

The Naya Breast Pump System may be used in the hospital or home setting. The Pump may be used by different users, but one person at a time. The Distal Breast Assembly (DBA) is intended as a single user component.

A reciprocating diaphragm vacuum pump, driven by a microprocessor, generates the suction to extract the milk at vacuum levels up to 260 mmHg. The Naya Breast Pump System is powered by a rechargeable battery or from mains.

The User Interface with the pump is:
- Power Button
- Mode Button
- Touch Wheel

The Mobile App looks identical to the pump user interface in that the same three interface points are present.

The device has two modes of operation:
- **Stimulation Mode**: Suction pattern with fast cycles and low vacuum to start milk flowing
- **Flow Mode**: Suction pattern with slower cycles and higher vacuum to express more milk gently and efficiently.

Indications for Use:
The Naya Breast Pump System is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts.

Patient Population: Lactating women

Environment of use: Home and / or hospital settings

Contraindications: None

Table 1 below presents a comparison between the proposed device and the predicate.

Substantial Equivalence Discussion of Comparison to Predicates

The Naya Breast Pump System is viewed as substantially equivalent to the predicate device because:

Indications –

- Indications for use are to express milk of lactating women

Discussion – These are the identical indications for use of the predicate – Medela – Symphony – K151632.

Technology –

- The technology of a reciprocating diaphragm vacuum pump to express milk and the flange and collection bottle system are similar to the predicate. The power source, user controls, ability to adjust vacuum level and pump mode are similar to the predicate.

Discussion – The technology and performance specifications for the proposed device are similar to the predicate - Medela – Symphony – K151632.

Materials –

- The materials which are in contact with the user and the expressed milk are considered by ISO 10993-1 as having the following classification:
- Surface contact, Intact skin, Limited duration (< 24 hours) tests performed included: Cytotoxicity, Intracutaneous reactivity, and Sensitization.

Discussion – The materials are similar and have been found to meet ISO 10993 requirements and thus can be substantially equivalent for safety as the predicate - Medela – Symphony – K151632.

Environment of Use –

- The environment of use, home and / or hospital is identical to the predicate.

Discussion – The environment of use is identical to the predicate - Medela – Symphony – K151632.

Patient Population –

- The patient population is lactating women is identical to the predicate.

Discussion – The user population is identical to the predicate - Medela – Symphony – K151632.

Non-Clinical Performance Testing Summary

We have performed a number of bench tests to demonstrate the Naya Breast Pump System performs within its specifications. These tests included:

- Breast Shield Assembly (BSA) Concentrated Cleaning
- Biocompatibility Test
- Software Verification
- ES 60601-1, IEC 60601-1-2, IEC 60601-1-11 Test
- Pump Drive Systems (PDS)
    - User Interface pre- and post- conditioning
    - Battery pre- and post- aging
- Breast Shield Assembly (BSA)
    - Fluid Isolation & Drainage
    - Functional pre- and post- aging
    - Conditioning Test
    - Lifetime Cycling

Materials –

The materials were tested as Surface contact, Intact skin, and Limited duration (< 24 hours): Cytotoxicity, Intracutaneous reactivity, and Sensitization. In addition the material contains no natural latex and are certified for food-contact in accordance with 21 CFR 174-179.

Discussion of Differences

The basic design, performance and features of the Naya Breast Pump System are similar to the predicate. The notable differences are:

- The ability to also control the device via a mobile App.
    - We have evaluated this App and it is configured to look and perform exactly like the interface on the pump.

These differences do not raise any new safety concerns and supports substantially equivalence.

Attribute	Proposed Naya Breast Pump System	Medela Symphony K151632
Intended Use	The Naya Breast Pump System is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts.	The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breast.
Patient population	Lactating women	Lactating women
Environment of use	Home and Hospital	Home and Hospital
OTC	Yes	Yes
Power Source	Input: 100-240 VAC, 50/60Hz, 2.1A 1 x 14.8V / 3200 mAh Rechargeable Li-ion Battery	Input: 100-240 VAC, 50/60Hz 0.3A 2 x 6V / 1.2 Ah Rechargeable Pb batteries
Pump Style	Reciprocating Pump	Diaphragm pump
Single/double Pumping	Both	Both
Adjustable Suction Levels	10 levels	16 levels
Cycle Speed	34 – 120	45 - 120
Overflow Protection	Yes (diaphragm)	Yes (diaphragm)
Vacuum range - double (mmHg)	50-250	75-200
Vacuum range - single (mmHg)	50-260	75-270
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor
Accessories	Flange (Breast Shield Assembly), including tubing, check valve and puck diaphragm Bottle (Collection Cup)	Flange / Soft Flange Tubing Check valve Diaphragm Bottle
Software	Yes	Yes
Cleaning method for Accessories	Soap and warm water	Soap and warm water Boiling water
Materials in contact with user and expressed milk tested per ISO 10993-1	Cytotoxicity Sensitization Intracutaneous	
Electrical Safety	ES60601-1 IEC 60601-1-2 IEC 60601-1-11 home use	UL 1431
Flange offered in multiple sizes	Yes	Yes

Table 1 – Comaprison of the Proposed Device ot the Predicate

Substantial Equivalence Conclusion

The Naya Breast Pump System is substantially equivalent to the above listed predicate and we have determined that there are no significant differences which would affect safety and efficacy for the patient population. This has been demonstrated through performance testing, design, and features, and non-clinical testing.