DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 28, 2017

Moxxly, Inc.
Rory A. Carrillo
Quality/Regulatory
1777 Yosemite Ave. Suite 235
San Francisco, CA 94124

Re: K170722
Trade/Device Name: Moxxly Flow
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 18, 2017
Received: July 24, 2017

Dear Rory A. Carrillo:

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 (DICE) 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 (DICE) 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170722

Device Name
Moxxly Flow

Indications for Use *(Describe)*
The Moxxly Flow breast pump collection system is intended to be used in conjunction with a compatible powered breast pump for the purpose of expressing human milk

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Submitter

Moxxly, Inc.
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San Francisco, CA 94124
Phone: (650) 416-6084
Email: cara@moxxly.com

B. Date Prepared

August 28, 2017

C. Contact Person

Rory A. Carrillo
Quality/Regulatory
Phone:
Email:

D. Device Name and Classification

Device Proprietary Name:	Moxxly Flow
Device Common Name	Powered Breast Pump
Device Classification: **Regulatory Class:** **Product Code**	21 CFR§884.5160 Class II HGX

E. Predicate Device

The Moxxly Flow is substantially equivalent to the DAO Health Freemie Breast Pump Collection System, K130349.

The predicate devices have not been subject to a design-related recall.

F. Intended Use

The Moxxly Flow breast pump collection system is intended to be used in conjunction with a compatible powered breast pump for the purpose of expressing human milk.

G. Device Description

Moxxly, Inc. is the manufacturer of the Moxxly Flow, a device intended to be used in conjunction with a compatible breast pump for the purpose of expressing human milk.

The Moxxly Flow consists of two collection units designed to be compatible with select

compatible electric breast pumps and provide a more comfortable design to aid collection of breast milk. The Moxxly Flow is provided non-sterile and is a single patient reusable device. The system should be cleaned by the user prior to use.

The device has a sloped flange (cup insert), flexible neck, internal valve assembly and low-profile bottle. Variations of the device incorporate minor differences to replicate the functional and performance characteristics necessary for use with additional pump brands.

The Moxxly device is designed to fit within a lactating woman's ordinary or nursing bra and held in place there while breast pumping. When the pump extracts milk, the milk flows out through the end of the flange, where it passes through the neck and valve system at the bottom of the bra and into the attached collection bottle. When the lactating woman is done pumping, she turns off the pump, removes the Moxxly device from under her clothes and transfers the milk to a storage container for later use.

H. Comparison of Indications for Use with Predicate Device

MFR **Model Name**	**DAO Health** **Freemie Breast Pump Collection System (K130349)**	**Moxxly, Inc.** **Moxxly Flow (K170722)**
Indications for Use	The Freemie breast pump collection system is intended to be used in conjunction with an approved powered breast pump for the purpose of expressing human milk.	The Moxxly Flow breast pump collection system is intended to be used in conjunction with a compatible powered breast pump for the purpose of expressing human milk.

The intended use is similar to that of the predicate device.

I. Comparison of Technical Characteristics with Predicate Device

MFR **Model Name**	**DAO Health** **Freemie Breast Pump Collection System**	**Moxxly, Inc.** **Moxxly Flow**
510(k) Number	K130349	K170722
Classification	21 CFR§884.5160	21 CFR§884.5160
Device Type	Pump, Breast, Powered	Pump, Breast, Powered
Product Code	HGX	HGX
User Population	Lactating Mothers	Lactating Mothers
Target Area	Breast	Breast
How Supplied	Non-sterile	Non-sterile
Single User	Yes	Yes
Cleaning Methods	Soap and warm water Dishwasher Boiling	Soap and warm water Dishwasher Boiling
Flange Size(s)	25mm 28mm 32mm	24mm (Medium) 27mm (Large)
Overflow Protection	Yes	Yes
Volume Capacity	16 oz	10 oz
Pump Compatibility	Yes • Pump in Style Advance • Medela Symphony • Lactina • Ameda Purely Yours • Twin Electric Breast Pump • Spectra Dew 300 • Spectra Dew 350	Yes • Ameda Purely Yours • Evenflo Advanced • Freemie Freedom • Hygeia Enjoye • Medela Pump In Style Advanced • Medela Symphony

The subject device and the predicate device do not have the same technological characteristics. The flange size, collection bottle size, material, and compatible pumps are different between the subject device and the predicate device.

The different technological characteristics of the subject device do not raise different safety or

effectiveness questions because all devices used for collection of breast milk in conjunction with breast must demonstrate that they are biocompatible and work in conjunction with the identified compatible breast pump.

J. Non-Clinical Performance Test Summary

Verification and Validation was conducted to demonstrate safety and effectiveness and for comparison to the predicate device. Testing included: flange design, compatible pumps, vacuum performance, capacity and freedom from leakage, and ability to be supported, usability, and biocompatibility. Test results established that the device meets its design requirements and intended use, that it is as safe, as effective, and performs as well as the predicate device. Testing data demonstrate the device meets all of its specifications including compliance with the following:

Biocompatibility:

- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: For In vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization

Usability:

- IEC 62366-1:2015 Medical Devices - Part 1: Application of Usability Engineering for Medical Devices

K. Conclusion

The Moxxly Flow is substantially equivalent to the predicate device.