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

February 20, 2015

Limerick, Inc.
Patricia Kelly
2150 N. Glenoaks Blvd.
Burbank, CA 91504

Re: K132220
Trade/Device Name: PJ's Serenity
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: February 2, 2015
Received: February 6, 2015

Dear Patricia Kelly,

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

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)*
K132220

Device Name
PJ's Serenity

Indications for Use *(Describe)*

The Electric Breast Pump, model PJ2012 is used to express and collect milk from the breast to alleviate engorgement of the breast, maintain the ability of lactation and provide mother's milk for future feeding when separation of mother and baby occurs. The device is intended for multiple users.

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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Submission Number **K132220/S004**

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2014/06/13
Submitter:	Limerick, Inc.
Primary Contact Person:	Patricia Kelly President Limerick, Inc. Tel: (818) 566-3060 Fax: (818) 566-1260
Secondary Contact Person:	Joan Ortiz Vice President Limerick, Inc. Tel: (818) 566-3060 Fax: (818) 566-1260
Device:Trade Name:	PJ's Serenity Model PJ2012
Common/Usual Name:	Powered breast pump
Classification Names:	Powered breast pump
Regulation Number:	CFR884.5160
Product Code:	HGX
Predicate Device(s)	K051926, PJ's Comfort breast pump K012275, PJ's Comfort portable breast pump

Submission Number **K132220/S004**

Device Description:	The Electric Breast Pump, model PJ2012 is designed and manufactured by Limerick, Inc. It is intended to express and collect milk from a lactating woman's breast. This action helps to alleviate engorgement of the breast, maintain the woman's ability to lactate, and provide a mother's milk for future feedings when separation of the mater and baby occur. The product uses a Single-Chip Microcontroller to imitate a baby's suckling action. The device is ergonomically designed to create comfortable milk stimulation, massage, and suction from the breast. There are 80 vacuum levels and 30 speeds available to imitate the rhythm and action of a baby's suckling. Selection of the vacuum and speed is made by adjusting the control knobs on the front panel of the pump. The control panel is soft and viewing is provided by a LCD screen. Once programmed, the pump's electronic memory stores the selected rhythm and intensity of the device.
Indications for Use:	The Electric Breast Pump, model PJ2012 is used to express and collect milk from the breast to alleviate engorgement of the breast, maintain the ability of lactation and provide mother's milk for future feeding when separation of mother and baby occurs. The device is intended for multiple users.
Technology:	The Electric Breast Pump, model PJ2012 is designed to mechanically interface with a mother's breast via breast shield and withdraw, then collect, the breast milk. The device incorporates a microcontroller with embedded firmware. The microcontroller is a Microchip PIC18F26K22. The firmware was developed using MicroEngineering Labs PICBasic Pro. The device incorporates a pump driven by an electric motor to produce a vacuum. The device incorporates an air valve to selectively allow air into the vacuum system. The device incorporates an LCD display to provide information to the user. The firmware provides a means for the user to start and stop pump operation.

While in operation, it provides a means for the user to adjust the speed of the pump motor and adjust the maximum vacuum level reached. The motor speed is controlled using pulse width modulation of the power applied to the motor. The maximum vacuum level is controlled by monitoring the output of a vacuum sensor and comparing the vacuum level with the user setting. When the level is reached, the air valve is opened. The LCD display shows the settings for the motor speed and vacuum levels using an arbitrary numeric scale, such as 1 to 30. The LCD also shows an elapsed time in minutes from the start of pump cycling.

Determination of Substantial Equivalence:

Specification	Predicate Device	Predicate Device	Proposed Device	Discussion of Differences
Device Name	PJ's Comfort	PJ's Comfort portable	PJ's Serenity	
K Number	K051926	K012275	K132220	
Indications for Use	The intended use of the electrically powered (diaphragm type) suction device is to express milk from the breast of lactating women.	The intended use of the electrically powered (diaphragm type) suction device is to express milk from the breast of lactating women.	The Electric Breast Pump, model PJ2012 is used to express and collect milk from the breast to alleviate engorgement of the breast, maintain the ability of lactation and provide mother's milk for future feeding when separation of mother and baby occurs. The device is intended for multiple users.	The Indications for Use statements between the subject and predicate devices are not identical, but the intended use of the devices—to express milk from the breast of lactating women—is the same.
Patient Population	Breastfeeding Women	Breastfeeding Women	Breastfeeding Women	Same
Pump Type	Diaphragm	Diaphragm	Diaphragm	Same
Vacuum Range	40-270mm Hg	150-220 mm Hg	15-270 mm Hg.	Similar
Cycle Levels	16-70 cycles/min.	30-45 cycles/min.	15– 275 cycles/min	The difference in cycle rate between the

				subject and predicate devices does not represent new technology, and raises no new types of safety and effectiveness questions.
Filter Between kit and pump	Yes	Yes	Yes	Same
Adjustable Suction Levels	Yes	Yes	Yes	Same
Software	Yes	Yes	Yes	Same
Anatomical Sites	Breast	Breast	Breast	Same
Energy Used And/or delivered	AC Battery Car adapter	AC Battery Car adapter	AC	No battery No Car adapter for PJ's Serenity as it is only used in hospital
Designed and Materials	All food or human contact components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177 and 178.	All food or human contact components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177 and 178.	All food or human contact components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177 and 178.	Same
Performance	Stimulation, suction and collect	Stimulation, suction and collect	Stimulation, suction and collect	Same
Standards Met	IEC60601-1 2005, 3rd Edition IEC60601-2: 2007, 3rd Edition ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC60601-1 2005, 3rd Edition IEC60601-2: 2007, 3rd Edition ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC60601-1 2005, 3rd Edition IEC60601-2: 2007, 3rd Edition ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Biocompatibility	Not cytotoxic irritating or dermal sensitizer	Not cytotoxic irritating or dermal sensitizer	Not cytotoxic irritating or dermal sensitizer	Same
Mechanical Safety	Electromechanical cycling suction regulator	Electromechanical cycling suction regulator	Electromechanical cycling suction regulator	Same

Operating Temperature	5-40 degree C	5-40 degree C	5-40 degree C	Same
Electrical Safety				
Bench Test	Performs within specifications	Performs within specifications	Performs within specifications	Same
1-Micron filter	Provides a barrier . against bacteria, fluid and virus from entering the pump	Provides a barrier against bacteria, fluid and virus from entering the pump	Provides a barrier against bacteria, fluid and virus from entering the pump	Same
Accessory Kit	2 silicone breast cups 2 braces 2 bottle caps 2 silicone gaskets 2 storage containers 2 tubes with "Y" adapter 2 tube connectors 1 filter 1clamp	2 silicone breast cups 2 braces 2 bottle caps 2 silicone gaskets 2 storage containers 2 tubes with "Y" adapter 2 tube connectors 1 filter 1clamp	2 silicone breast cups 2 braces 2 bottle caps 2 silicone gaskets 2 storage containers 2 tubes with "Y" adapter 2 tube connectors 1 filter 1clamp	Same
Packaging	Corrugated	Corrugated	Corrugated	Same

Summary of non-clinical tests:

The sponsor has performed bench testing to demonstrate the electric breast pump performs within the specifications:

PJ's Serenity Model number PJ2012
Vacuum levels 15-270 mm Hg.
Cycles/min 15 – 275 cycles/min

PJ's Serenity Model number PJ2012 has met acceptance criteria of performance testing including: biocompatibility (in vivo cytotoxicity, irritation, and sensitization testing), software validation, EMC, electrical safety, and vacuum pressure / cycle rate testing.

Conclusion:

Limerick, Inc considers the PJ's Serenity electric breast pump to be substantially equivalent to the predicated devices.