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

December 22, 2015

Powers Medical Devices, LLC
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc,
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K151050
Trade/Device Name: Pacifier Activated Lullaby (PAL®)
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: HCC
Dated: November 24, 2015
Received: November 25, 2015

Dear Sharyn Orton:

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 (Part 809); 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 (Part 809), 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,

William J. Heetderks -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K151050

Device Name
Pacifier Activated Lullaby ("PAL®")

Indications for Use *(Describe)*
The Pacifier Activated Lullaby (PAL®) encourages and reinforces effective non-nutritive sucking of premature infants. This is accomplished by giving positive feedback to the infant in the form of music or a mother's voice as auditory input in direct response to sucking.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K151050

A) Submitted by: Powers Medical Devices, LLC
1615 S. Congress Ave, Ste 13
Delray Beach, FL 33445

Official Contact: Patricia Palmer, CEO
Powers Medical Devices

Date prepared: November 21, 2015

B) Device Name: Device, Biofeedback
Proprietary Name: Pacifier Activated Lullaby ("PAL®")
Device Class: Class II
Regulation number: 21 CFR 882.5050
Regulation name: Biofeedback device
Product code: HCC
Classification panel: General & Plastic Surgery

C) Predicate: K010388 P.A.L. System Ohmeda Medical

D) Device Description:

The Pacifier Activated Lullaby ("PAL®") has a player module, pacifier sensor module and power supply. The pacifier sensor module senses the strength and duration of an infant's sucking on an attached pacifier and responds with music or a recorded sound (i.e. mother's voice) contingent to the infant's sucking. The pacifier module consists of a wired transmitter with a built in pressure transducer that connects to the pacifier and a receiver. The receiver decodes the signal and plays music or a recorded sound for a predetermined length of time via a speaker to the infant contingent on his/her sucking on the pacifier transmitter. This action occurs when the sucking strength and duration exceeds preset values. The user can control the sensitivity of the transducer.

This application describes modifications to the FDA cleared K010388 P.A.L. System.

E) Indications For Use:

The Pacifier Activated Lullaby (PAL®) encourages and reinforces effective non-nutritive sucking of premature infants. This is accomplished by giving positive feedback to the infant in the form of music or mother's voice as auditory input in direct response to sucking.

F) Substantial Equivalence Comparison and Discussion

The Pacifier Activated Lullaby (PAL®) has the same Indications for Use and basic functionality as the predicate device. Modifications to the device include changes to the speaker configuration and pacifier to control unit transmitter and associated software changes, as well as technology updates. Differences do not raise different issues of safety or performance, and issues of safety are assessed in the risk analysis. The Pacifier Activated Lullaby (PAL®) is expected to perform per its Indications for Use and is substantially equivalent to the predicate device.

G) Biocompatibility

All patient contacting materials used in the PAL are biocompatible

H) Sterilization and reprocessing

NA – No component is provided sterile and the pacifier sensor module is single use, disposable.

I) Performance Testing

Performance testing included the following:

- Software verification and validation
- Electrical/EMC
- PAL unit stability and sensor wire positioning

Compliance with the following standards, regulations or guidelines:

- AAMI ES 60601-1, 2005/(R) 2012 and A2: 2010/(R)2012: Medical Electrical Equipment
- IEC 60601-1-2:2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- FCC Part 15 Subpart B
- ICES-003 Issue 4 for a Class B Device – Digital apparatus
- ISTA-6 Testing Packaging Product Weighing up to 150 lbs

Conclusion

The Pacifier Activated Lullaby (PAL®) performs per its Indications for Use and is substantially equivalent to the predicate device.