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

September 9, 2015

NFANT Labs, LLC
% Julie Stephens
Consultant
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, GA 30004

Re: K143507
Trade/Device Name: NFANT® Feeding Solution
Regulation Number: 21 CFR §882.5050
Regulation Name: Biofeedback device
Regulatory Class: II
Product Code: HCC
Dated: August 6, 2015
Received: August 7, 2015

Dear Julie Stephens,

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,

Herbert P. Lerner -S

for 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)*
K143507

Device Name
NFANT® Feeding Solution

Indications for Use *(Describe)*
NFANT® Feeding Solution is intended to measure movement of the nipple during non-nutritive suck (NNS) or nutritive suck (NS).

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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NFANT Labs, LLC
Traditional 510(k) # K143507 - NFANT® Feeding Solution

510(k) SUMMARY

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

Submitted By: NFANT Labs, LLC
817 West Peachtree St. - Suite 320
Atlanta, GA 30308
Phone: (404) 395-0725

Contact Person: Julie Stephens - Regulatory Resources Group, Inc.
Regulatory Consultant

Date Submitted: August 6, 2015 - Revised September 3, 2015

Device Name and Classification:

Trade/Proprietary Name:	NFANT® Feeding Solution
Common Name:	Infant Feeding Measurement Device
Classification Name:	Biofeedback Device
Product Code:	HCC
Regulation and Class:	21 CFR 882.5050; Class II

Legally Marketed Predicate Device:

NTrainer System® - KCBioMedix, Inc. (now owned by Innara Health) - 510(k) # K071866

Device Description:

NFANT® Feeding Solution is comprised of a portable multi-use electronics unit (NFANT SSB Sensor) powered by a non-rechargeable coin cell battery, single use bottle coupling (NFANT Coupling) and mobile application which acts as a user interface and data display (NFANT App). Nipple movement data during Non-Nutritive Suck or Nutritive Suck is transmitted to a mobile device and displayed for clinician interpretation. Information from past feedings can also be securely transferred, stored and retrieved by authorized users from a cloud based database (NFANT DBMS) for comparisons between feedings.

When in use, the NFANT Coupling has a commercially available or prescribed bottle or pacifier nipple placed on one end and a normal bottle on the other. The NFANT SSB Sensor is snapped in place to mate with the NFANT Coupling. The user “wakes-up” (activates) NFANT SSB Sensor for streaming and data collection. An infant then undergoes normal non-nutritive sucking with a pacifier (no liquid swallow) and/or nutritive sucking with a bottle nipple during normal feeding sessions (liquid swallow). Nipple movement data is garnered and displayed on the mobile application for clinical interpretation. Safe oral feeding requires coordination of sucking, swallowing and breathing which involves integration, maturation and coordination of multiple sensorimotor systems. NFANT provides clinicians with objective data regarding nipple movement during non-nutritive (NNS) and nutritive sucking (NS).

As the infant sucks, the NFANT Coupling allows bottle fluid (when applicable) to flow from the bottle to the nipple. The NFANT Coupling maintains a plug insert that provides a two compartment membrane sealing the NFANT Coupling and separating the bottle fluid from pressure sensors contained in the NFANT SSB Sensor housing. With assembly, ports on the NFANT SNAP housing engage each respective membrane creating a seal between the

NFANT Labs, LLC
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NFANT SSB Sensor and NFANT Coupling while also creating two sealed chambers between the membrane and a respective pressure sensor.

NFANT has one disposable component, the NFANT Coupling that comes in contact with the fluid. After a single use by a patient, the NFANT Coupling is disposed of in waste. The NFANT SSB Sensor does not come in contact with the feeding fluids and is reused specific to the infant with each NFANT Coupling usage. The NFANT App component is software only. NFANT is sold non-sterile.

Indications for Use:

NFANT® Feeding Solution is intended to measure movement of the nipple during non-nutritive suck (NNS) or nutritive suck (NS).

Similarities and Differences to the Predicate Devices:

Similarities

Most of the same types of materials (plastics, electronics, etc.), the same performance functions, and the same indications for use specific to the passive assessment of non-nutritive suck are used in NFANT Feeding Solution and the predicate device. Both the NFANT and the predicate device couple with commercially available pacifier nipples and they both use pressure sensors located within the electronics unit coupled onto the pacifier nipple to make passive assessment measurements of infant non-nutritive sucking (NNS). Both the NFANT Feeding Solution and the predicate device display the NNS data for clinician interpretation or assessment on a computing device.

Differences

The differences in materials (plastics, electronics, etc.) and performance functions does not affect the safety and efficacy of NFANT Feeding Solution in comparison with the predicate device. The NFANT Feeding Solution indications for use include passive assessment measurements during nutritive suck (NS) because the NFANT Feeding Solution is not limited to just pacifier nipple use but the predicate device is limited to only pacifier nipple use. The NFANT sensors never come in contact with feeding fluid so it can be used with a bottle nipple coupled with fluid bottle. The NFANT Feeding Solution has separate sensors for nipple movement and ambient pressure measurement. The predicate product's sensors only come in contact with air within the nipple (*i.e.,* measurement of movement) and do not couple with bottles for feeding. NFANT sensors also only come in contact with air but are located outside of the nipple cavity separated by a membrane. Transmission is wireless and NFANT SSB Sensor is powered only by a coin cell battery rather than plugging into a powered motorized cart unit as is required with the predicate device. The NFANT Feeding Solution is a passive measurement system. The predicate device measures and has an "active therapy" mode which alters pressure dynamics.

Summary of Testing:

The NFANT Feeding Solution was tested as directed by FDA guidance under ISO 10993-1 biocompatibility requirements and passed. Bench testing completed for the NFANT Feeding Solution included preliminary tests to 1) Verify proper seals of the NFANT SSB Sensors and NFANT Assembly to enable pressure measurements; 2) Calibrate known pressure inputs to NFANT SSB Sensor output; 3) Measure nipple dynamics for clinical interpretation; and 4) Validate accelerometer tilt readings to known angular inputs to determine NFANT Assembly

510(k) SUMMARY

orientation. Shelf life testing was completed under accelerated aging and will continue under real time aging. Software verification and validation included testing for the three software components for the NFANT Feeding Solution specific to the embedded firmware, the NFANT App, and the Web Portal used within the NFANT Database and Management System.

Substantial Equivalence Conclusions:

All of the testing results for the NFANT Feeding Solution passed within the acceptance parameters and demonstrated a safe and reliable device for measuring nipple movement of the nipple using pressure sensors. The NFANT Feeding Solution will consistently and accurately make these measurements and display them for the clinician to interpret during non-nutritive suck (NNS) or nutritive suck (NS). While the predicate device, in addition, is active in that it alters pressure dynamics through use of air inflation to the pacifier nipple, the additional feature of the predicate device does not change the substantial equivalence that both devices assist the clinician in their assessment of the premature infant's ability to suck through nipple movement.