K071866

Appendix B

510(k) Summary

KC BioMediX, Inc.
Improving Neonatal Care

510(k) Summary – NTrainer

January 25, 2008

510(k) Owner - KCBioMedix, Inc.
Michael Litscher, President & CEO
8960 Commerce Drive
Suite 5C
Desoto, KS 66018
785.856.2021
Email: mlitscher@kcbiomedix.com
785.832.8234 (fax)

FEB - 1 2008

Contact person:
Stanley Consulting, LLC
Jim Stanley, Principal Consultant
4200 SW Sapelo Drive
Lee's Summit. MO 64082
Phone 816.550.4510
Email: stanleyconsulting@comcast.net

- Trade Name – NTrainer System
- Common Name – There is no common name for this device (or feeding therapy device)
- Classification Name - Biofeedback device (21 CFR 882.5050, Product Code – HCC)

Predicate Devices

There are two predicate devices. The Sondrex P.A.L System (K010388) is a pacifier system and method for reinforcing non-nutritive sucking (NNS) of premature infants and the Ultramind Biofeedback System (K980373) is an apparatus and software designed to train the user to control one or more aspects of their psycho-physiological state including the autonomic nervous system.

Description of the NTrainer Device

A Soothie™ pacifier is inflated by a low pressure air pump that stimulates the baby's lips, tongue and jaw thus allowing the NTrainer System to reinforce non-nutritive suck

(NNS) in newborns and infants. This is accomplished by providing the newborns or infants with a synthetic patterned oral somatosensory input.

There is a central pattern generator in the brain and when normally developed provides the baby with a non-nutritive suck which is an essential building block in an infant's development of the coordinated sucking, breathing and swallowing capability needed for independent oral feed.

The NTrainer represents an integrated cribside application to assess and entrain the orofacial motor systems (lips, tongue and jaw). The baby is provided with a synthetic suck patterned by imposing rhythmic changes in the pacifier nipple which causes a reflex action in baby who adapts the suck pattern.

The NTrainer consists of the motor assembly, air cylinder, control electronics and computer system including a display. The only interface and contact with the baby is the disposable Soothie Pacifier.™

The application software has two modes of operation, NeoSuck, the assessment mode which defines the baby's state of non-nutritive suck development and, NTrainer, the therapy mode which reinforce the development of non-nutritive suck. NTrainer and NeoSuck application software were originally developed by programmers at the University of Kansas (KU). This software has been reviewed and determined to be software having a "Minor Level of Concern" in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Indications for Use: The NTrainer System reinforces non-nutritive suck (NNS) in newborns and infants born prematurely.

Intended use

Oral feeding competency is one of the most frequent and challenging hurdles facing many premature babies with respiratory disease and / or brain insult. Premature infants often lack a functional non-nutritive suck (NNS) or delayed suck patterning, dyscoordination of suck, swallow, breathe and poor state control. The lengthy intubation / oxygen supplementation procedures cost the baby precious sensory and motor experiences during a critical period of brain development for oromotor pattern generation.

The NTrainer system reinforces non-nutritive suck (NNS) in newborns, from birth (premature) to 1 month of age and in infants greater than 1 month. This is accomplished by providing the premature baby with a synthetic patterned oral somatosensory input. The intended target population is "newborns and infants, born prematurely with a gestation age (GA) greater than 25 weeks and lacking an organized NNS".

One predicate device, the Sondrex P.A.L. System, reinforces non-nutritive sucking of premature infants by playing music while the NTrainer System reinforces non-nutritive suck (NNS) in newborns (premature) and infants by providing the baby with a synthetic patterned oral somatosensory input.

The other predicate device, the Ultramind Biofeedback, is a biofeedback system is used for relaxation training while the NTrainer provides input to reinforce non nutritive suck.

There are no known risks associated with low-level mechanical stimulation, or recording low-level force (pressures) in the orofacial mechanism. Oral stimulation strategies have proven beneficial in developing oral feeding performance in premature infants (Fucile, Gisel, Lau, 2002, 2005; Rocha et al., 2006).

Technical Characteristics and Predicate Devices

The Sondrex PAL System predicate is a pacifier system and method of therapeutically treating premature infants to reinforce non-nutritive sucking. A pacifier is connected to a pressure transducer. The pressure transducer serves to detect sucking intensity and the duration of the suck. The pacifier system activates a sound source, such as a music source, upon sucking of a minimum intensity being detected for a minimum period of time. The sound (music) is intended to reinforce the non-nutritive sucking.

The Ultramind Biofeedback System with de-Stress software predicate is an apparatus and program designed to train the user to control one or more aspects of their psycho-physiological state including the autonomic nervous system.

The NTrainer System is a pacifier system for assessing and a method of therapeutically stimulating the human orofacial system to reinforce non-nutritive sucking. The system includes a pacifier connected to an air cylinder with an integrated pressure transducer. In the assessment mode the pressure transducer serves to detect sucking intensity and time (frequency) of the suck. In the therapy mode the NTrainer Systems provides patterned, rhythmic stimulation to the infant's orofacial system to stimulate and entrain brain development.

Based on the technical comparison in the Substantial Equivalence Comparison (Section IV), the minor difference between the NTrainer System and the Sondrex PAL System is in the therapy mode. The NTrainer energy source for therapy is very low air pressure that is running about 105 cm H_2O or about 1.5 psi with an air volume no greater than 2 cc's, to deflect the nipple cylinder. If the pacifier were to come loose or come off, the local pressure gradient proximal to the aperture on the receiver bulb would drop off steeply within a few millimeters to approach atmospheric pressure.

Technically, in the assessment mode, the NTrainer operates like the PAL. It uses all the same system elements including the measurement of the suction the baby creates while

sucking on the nipple. The difference is the NTrainer converts the signal to a waveform that is shown on a display instead of triggering music to be played.

Based on the technical comparison in the Substantial Equivalence Comparison the minor difference between the NTrainer System and the Ultramind Biofeedback System is in the assessment mode. The Ultramind Biofeedback system measures galvanic skin response in comparison to the NTrainer measuring the suck pressure on the nipple measured through a pressure transducer. The patient contact for the Ultramind Biofeedback System is a finger electrode versus a pacifier nipple for the NTrainer. The pacifier nipple is a commonly used device in the NICU without any known risk

Non Clinical Performance Data

Executive Summary – Bench Tests

There are three key functional tests that were run as part of the assembly and test of each NTrainer: The performance test of the hand piece, the test and calibration of the Pneumatic Generator Assembly (PGA) and the final test of the finished device.

Handpiece

Using the NeoSuck-RT program the test session was ran to obtain a display showing that the pressure transducer's response was to specifications and it did not leak.

Pneumatic Generator Assembly

The components of the Pneumatic Generator Assembly (PGA) are used to create the pressure pulse fed to the nipple to entrain the baby. The servo controller and the linear motor were aligned and adjusted to specification. A wave form was captured which confirmed that the system was functioning properly.

Final System Performance Test

The NTrainer-RT program and NeoSuck-RT program were ran to verify they are operation properly. The displayed wave forms were captured, printed and compared to the requirements. The results met specifications.

In the therapy mode a test sequence was ran to confirm the device is producing the correct frequency and amplitude of the entraining pulses. The expansion of the nipple was sampled and confirmed that the amplitude is correct.

Clinical Performance Data

The following clinical results are derived from the clinical study that included 30 newborns with moderate-severe Respiratory Distress Syndrome. 20 RDS newborns were provided NTrainer therapy (the RDS Test group) and 10 RDS newborns did not receive therapy as the control group (the RDS Control group).

The RDS Test infants were given a 3 minute therapy session at each feeding. Typically the training was accomplished over a 7 day period of time.

Numerous performance factors were measured to quantify how the improvement was measured. The performance factors included:

- Increase in NNS burst cycles / minute
- Increase in mouthing event / cycles / minute
- Increase in NNS bursts / minute
- Increase in NNS cycles / burst
- Increase in NNS cycles (% of mouthing)
- Reduction in non-NNS events / minute

Conclusion

In conclusion we have demonstrated that the NTrainer is as safe, as effective and performs better than the Sondrex PAL System in entraining NNS in newborns and infants. Our clinical study showed that entraining is accomplished by providing the baby with a synthetic patterned oral somatosensory input. Additionally there were no adverse events during the study.

The only clinical data found for the Sondrex PAL Systems was in the Journal of Music Therapy: Vol. 42, No. 2, pp. 123 – 139. (Effects of the Pacifier Activated Lullaby on Weight Gain of Premature Infants). During a 2-year time period, 62 infants from a sample of 188 met the criteria for analysis but showed no significance in daily weight gain for the number of PAL trials completed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

KCBiomedix, Inc
% Mr. James Stanley
Stanley Consulting, LLC
4200 Southwest Sapelo Drive
Lees Summit, MO 64082

Re: K071866
Trade/Device Name: NTrainer System
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: HCC
Dated: January 25, 2008
Received: January 28, 2008

Dear Mr. Stanley:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071866

Device Name: NTrainer System

Indications for Use:

The NTrainer System reinforces non-nutritive suck (NNS) in newborns and infants born prematurely.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071866