TAB 5

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510(K) SUMMARY

Official Contact

Scott Wright
Senior Regulatory Affairs Engineer
Children's Medical Ventures LLC
191 Wyngate Drive
Monroeville, PA 15146
Scott.Wright1@philips.com

412-380-8812 t
724-681-2407 c
412-380-8850 f

Date of Submission	November 22, 2010
Classification Reference	21 CFR 868.5905
Product Code	BZD – ventilator, non-continuous (respirator)
Common/Usual Name	CPAP System
Proprietary Name	NeoPAP System
Predicate Device(s)	Guardian Neonate CPAP / Humidification System (K040862)
Reason for submission	Modified Device

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Similar intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Children's Medical Ventures LLC NeoPAP System as a result of the risk analysis and product requirements. Children's Medical Ventures LLC has

determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 2006.

Formal test protocols were written and executed to verify and validate the modified NeoPAP System. All tests that were created for the modified NeoPAP System had passing results with acceptance criteria successfully met, which demonstrates the safety & effectiveness of the system.

Testing included software code reviews, software unit testing, software integration testing, bench verification testing, biocompatibility testing, environmental testing, user manual/labeling inspection, drawing inspections, and a clinical simulation (usability testing). Testing confirmed that the NeoPAP System performs equivalently to the predicate device (Guardian Neonate CPAP / Humidification System, K040862). All tests had acceptable results or discrepancies that do not impact safety or effectiveness.

Intended Use

The NeoPAP System is intended to provide continuous positive airway pressure (CPAP) for use in hospitals to treat newborns and infants, weighing less than 5 kg, with RDS or who are recovering from RDS. (Respiratory Distress Syndrome). The intended use of the NeoPAP System is unchanged from the predicate device (Guardian Neonate CPAP / Humidification System, commonly referred to as NeoPAP System, K040862).

Device Description

The Children's Medical Ventures LLC NeoPAP System provides nasal CPAP (continuous positive airway pressure) as a non-invasive method of breathing support for infants and newborns with compromised respiratory systems who weigh less than 5 kg.

The NeoPAP System provides CPAP therapy delivered to patient through a nasal cannula or mask. The system has a feature called Baby-Trak which actively regulates pressure at all times by monitoring pressure at patient's nose and adjusting flow from oxygen and air gas supplies using proportional solenoids. The Baby-Trak feature eliminates the need for a closely-fitted patient interface that can damage fragile tissues.

In addition to CPAP mode, the NeoPAP System offers a constant flow mode where the device delivers a fixed flow of humidified air/oxygen mixture through the nasal prongs or mask. There is also

a resuscitation mode where the device delivers a fixed flow of unhumidified air/oxygen through the resuscitation port for use with a resuscitation or hyperinflation bag. The percentage of oxygen can be adjusted while in any mode by using a rotary knob on the user interface.

The NeoPAP System alarms when pressure levels or oxygen concentration are above or below alarm limits. The system also detects occlusion, disconnect, and other alarm conditions. The system displays a real-time bar graph that indicates delivered pressure.

Predicate Comparison

The fundamental scientific technology of the NeoPAP System is unchanged from the predicate device (K040862). Children's Medical Ventures LLC has made the following changes to the previously cleared NeoPAP System to be considered for this submission:

- Flow Mode -- Flow Mode for the previously cleared system only delivered flow into an oxygen hood, whereas the modified system enables the device to deliver a constant flow of oxygenated gas through a nasal cannula or mask. In the modified system, the process for adjusting flow settings was modified to match the process of adjusting pressure settings in CPAP Mode. Both processes now utilize a rotary knob.
- Resuscitation Mode – The previously cleared system could only deliver 100% oxygen to the patient while in Resuscitation Mode. Since research has shown that high levels of oxygen for an extended period of time can lead to eye damage, the modified system is capable of delivering a range of oxygen concentration between 21 – 100% while in Resuscitation Mode.
- Aesthetics – The external design of the device has been modified to better align with the Philips brand image.
- User Interface – The user interface (UI) of the modified device was changed to emphasize ease of use and to be more intuitive than the original design. Key changes are the addition of a flashing alarm bar, removal of the flow segment display, replacement of the majority of membrane keys with capacitive touch keys, and the addition of pressure, FiO_2, and battery status LEDs changing from white to red when a specific parameter causes an alarm. These changes allow for a less cluttered appearance and more visible feedback for the user to determine what parameter is in an alarm state.
- Occlusion Alarms – Software was modified so that occlusion alarms only cause gas delivery to stop in the case of high manifold or patient pressure. It is no longer halted in the case of flow readings being lower than expected. The software was also modified so that all occlusion alarms auto-reset. Once the trigger for the alarm is no longer present, the occlusion flag is clear and gas delivery will automatically restart if it had been halted.

- User Confirmation After Turning Rotary Knobs – Software was modified so that the user must confirm that settings should be changed after turning the O_2 or pressure/flow setting control knobs. This will prevent inadvertent changes to settings.

- Humidification – The original NeoPAP System utilized a Vapotherm humidification cartridge which was internal to the device and a delivery circuit that utilized a heated water jacket to minimize rainout within the delivery line. However, due to Vapotherm's recall of the cartridge for potential of bacterial growth, the NeoPAP System was voluntarily recalled after less than a year on the market. For this reason, the modified NeoPAP System does not contain an internal humidifier, but is instead compatible with an external humidifier. The humidifier that is currently being demonstrated to be compatible with the NeoPAP System is the Fisher & Paykel MR850 Humidifier (K073706).

- Battery Life– The stand-alone battery life of the modified system is 2-hours instead of 1-hour as in the original NeoPAP System. The longer battery life will be useful in the event that power is lost and a back-up generator is not available or that the device is used during intra-hospital transport with no AC outlet available.

- Standby Mode – The original NeoPAP System did not have a Standby Mode. It was added to the modified NeoPAP System to accommodate system set-up prior to patient receiving therapy and care procedures where the patient is taken off of the device for a period of time.

- Configuration Menu – For both the original and modified NeoPAP System it is necessary to power off the device in order to enter the configuration menu. In order to allow the clinician to more easily adjust alarm parameters, several items were moved from the configuration menu to the delivery mode menu. The items that were moved are leak delay, high pressure delay, low pressure delay, pressure alarm band, and FiO_2 alarm band.

- Device Packaging -- The original device was packaged using foam inserts. The modified device utilizes suspension packaging which suspends the device in the airspace of the shipping container between two layers of highly resilient, low-slip film.

- Patient Interface Circuit – The original NeoPAP System patient interface consisted of a "generator" circuit into which the clinician would plug nasal prongs or nasal masks of an appropriate size for their patient. The tubing came over the top of the patient's head and between the eyes. The modified patient interface (commonly referred to as the PI2 System) consists of a one-piece cannula and one-piece mask. The tubing comes from both sides of the patient's head similar to an adult patient on oxygen. Additionally, a pressure tap was added to the most proximal part of the patient interface (at the patient) to allow the NeoPAP

System to better respond to changes in patient pressure to maintain the pressure level set by the clinician.

- Patient Interface Sizes/Shape – Masks are still available in 2 sizes and are unchanged from the original NeoPAP System in terms of overall footprint/outline. Cannulas are still available in 5 sizes and are unchanged from the original NeoPAP System in terms of prong spacing and prong diameter. The shape of the nasal prongs have been modified from a flare shape to a tapered shape for ease of manufacturing.
- Patient Interface Tubing and Connections –The pressure and delivery tubing in the original NeoPAP patient interface was surrounded by a water jacket. It was connected via a slip fit to the patient tubing. The PI2 System utilizes corrugated delivery tubing packaged standard for Fisher & Paykel RT324 humidification circuits with a heated wire to minimize condensation so that a water jacket is not necessary. The pressure line is permanently bonded to the exhalation body to prevent misconnection. The patient tube is permanently bonded to a cork that plugs into the exhalation body.
- Patient Interface Exhalation – The original NeoPAP patient interface had a series of holes in the tubing located about 7 inches from the patient. Instead of holes in the tubing, the PI2 has an exhalation body located about 15 inches from the patient with three large openings on different faces of the body so that the exhalation is not easily blocked regardless of orientation.
- Patient Interface Pop Off Valve – The original NeoPAP patient interface had an umbrella valve located directly at the patient in the generator which held the prongs or mask. The PI2 System utilizes the exact same valve made by the same supplier, but it is located in the exhalation body delivery air path.
- Patient Interface Bonnet – The original NeoPAP patient interface included a cotton bonnet available in 12 sizes to secure the "generator" circuit. The PI2 System includes a bonnet available in 5 sizes with a hook and loop material to adjust the fit. It has a unique foam material on the inside lining to minimize shifting of the bonnet and adjustable bonnet clips to hold the PI2 tubing in place.
- Patient Interface Usage Type: The device manual of the original NeoPAP System specified that the delivery tube, patient tube, and bonnet were single patient use while the nasal prongs and mask were single use. The device manual for the modified NeoPAP System indicates that entire patient interface is single patient use and lists acceptable agents/procedure for cleaning the exterior of the patient interface.

Table 1 (follows) compares the NeoPAP System with the predicate device.

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
Intended Use	Intended to provide CPAP for use in hospitals to treat newborns and infants with RDS or are recovering from RDS. (Respiratory Distress Syndrome) May or may not include humidification capabilities	Unchanged from K040862, other than rewording. The NeoPAP System is intended to provide continuous positive airway pressure (CPAP) for use in hospitals to treat newborns and infants, weighing less than 5 kg, with RDS or who are recovering from RDS (Respiratory Distress Syndrome).
Intended Environment of Use	Hospital	Unchanged from K040862.
Patient Population	Infants with or recovering from RDS weighing less than 5 kg.	Unchanged from K040862.
Product Code	BZD	Unchanged from K040862.
Operating Mode Descriptions and Ranges		
Gas Delivered	Air / Oxygen Mixture	Unchanged from K040862.
CPAP Mode – Description	Device actively regulates pressure at all times by monitoring pressure and adjusting flow from air and O_2 supplies using proportional solenoids.	Unchanged from K040862.
CPAP Mode – Delivery Location	Nasal prongs / mask.	Unchanged from K040862.
CPAP Mode – Range of Pressure	2 to 10 cmH_2O	Unchanged from K040862.
CPAP Mode - $\%O_2$ Range	21 – 100%	Unchanged from K040862.
Flow Mode – Description	Device delivers fixed flow of humidified air/oxygen mixture.	Unchanged from K040862.

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
Flow Mode – Delivery Location	Oxygen hood.	Nasal cannula / mask.
Flow Mode – Range of Flow	5 to 15 L/min	5 to 10 L/min
Flow Mode - $\%O_2$ Range	21 – 100%	Unchanged from K040862.
Resuscitation Mode – Description	Resuscitation Mode provides un-humidified gas through the resuscitation port for use with a resuscitation or hyperinflation bag.	Unchanged from K040862.
Resuscitation Mode – Fixed Flow	10 L/min	Unchanged from K040862.
Resuscitation Mode - $\%O_2$ Range	100%	21 - 100%
Standby Mode	No	Yes
Humidification Method	Vapotherm Microporous Membrane	The Fisher & Paykel MR850 Humidifier (K073706) has been demonstrated to be compatible with the NeoPAP System in this submission.
Range of Temperature of Gas Delivered	33 to 41 °C	The F&P MR850 humidifier does not have communications with the NeoPAP device so the temperature is set on the humidifier instead of the NeoPAP device.
User Interface / Display of Measured Data		
Circuit Pressure (bar graph display) Range	0 – 12 cmH_2O	Unchanged from K040862.
$\%O_2$ (window display) Range	21 – 100%	Unchanged from K040862.
Gas Temperature Range	10 to 50 °C	The F&P MR850 humidifier does not have communication with the NeoPAP device so the measured gas

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
		temperature will only be displayed on the humidifier and not on the NeoPAP device.
Flow (bar graph)	Indicator only – indicates that patient is inhaling / exhaling but does not give actual flow reading.	Flow bar graph removed to prevent confusion and provide a less cluttered appearance.
Alarms	High / Low Air Supply Pressure High / Low O_2 Supply Pressure High / Low FiO_2 High / Low Flow (Flow mode only) High / Low Pressure (CPAP mode only) High / Low Temperature High / Low Water Pressure No Water Supply No AC Power No O_2 Sensor Battery Not Present Low Battery Replace Battery Pressure Unstable (CPAP mode only) Partial Occlusion Occlusion Leak Unexpected Restart Miscellaneous System Error Alarms	Unchanged from K040862 with the exception that the NeoPAP device does not have communication with the F&P MR850 humidifier so the NeoPAP will not alarm for high / low gas temperature, high / low water pressure, or no water supply. However, the humidifier has its own alarming system for high / low gas temperature.
Alarm Visual Indicator	Backlit outline of a red bell.	Flashing alarm bar. Additionally, pressure and FiO_2 readings that are typically displayed using white LEDs change to red so that the user can more easily determine which of the parameters is in an alarm state.

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
System Halt Conditions	Mains power disconnected Air or O_2 supply pressure over 93 psi Internal battery voltage depleted High pressure detected during startup Delivery tube disconnected during operation Ambient temperature out of range Tube occluded during system start up Other miscellaneous halt conditions	Unchanged from K040862.
Input Types	Rotary knobs and membrane keys.	Rotary knobs, membrane keys, and capacitive keys.
Configuration Menu Access	Turn off device and power on while holding the Alarm Reset key.	Unchanged from K040862.
Configuration Menu Items	Alarm Sound Gap Auto-Reset Setting Patm Language Leak Delay High Pressure Delay Low Pressure Delay Pressure Alarm Band Temperature Alarm Band FiO_2 Alarm Band	Alarm Sound Gap, Auto-Reset Setting, Patm, and Language remain in Configuration Menu, and Leak Delay, High Pressure Delay, Low Pressure Delay, Pressure Alarm Band, and FiO_2 Alarm Band where moved to the Delivery Mode Menu so they could be accessed without powering off the device. Temperature Alarm Band item does not exist in current software since the F&P MR850 humidifier does not have communication with the NeoPAP device so it will not alarm for high / low gas temperature.
Features		

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
Power	AC and Battery	Unchanged from K040862.
Stand-alone Battery Life	1 hour	2 hours
Oxygen Sensor	Ventrex Oxygen Sensor (K963415)	Maxtec Oxygen Sensor (K972992).
Oxygen Sensor Location	Mixing block upstream of vapor transfer cartridge	Moved to pressure manifold block to allow FiO_2 to also be measured in Resuscitation Mode.
Patient Interface		
Usage Type	Delivery tube, patient tube, bonnet, are single patient use. Nasal prongs / mask are single use.	All components are single patient use. The entire patient interface can be cleaned and reused on the same patient.
Sterility Condition	Non-sterile	Unchanged from K040862.
Interface Design	Nasal prongs/mask is snapped into "generator" which is connected to dual lumen tubing that is routed above the nose (secured by a clip integral to the hat) to over the top of the head.	Nasal cannula/mask is one-piece molding that is connected to dual lumen pressure/delivery tube and single lumen exhalation tube that are routed to the sides of the head (secured by bonnet clips) and then over the head.
Exhalation Management	Series of holes in tubing approximately 7 inches from patient. Tubing must be oriented correctly so that holes are not blocked.	Exhalation body approximately 15 inches from patient with 3 large openings on different facets of the exhalation body so that exhalation is not easily blocked regardless of orientation.
Patient Pressure Measurement Location	At connection between delivery/pressure tubing and patient tube (approximately 10 inches from patient).	At most proximal point of patient interface (closest to patient) to provide most accurate readings.
Pressure Relief Valve Location	Located directly at the patient in the "generator" which holds nasal	Located in the exhalation body delivery air path approximately 15 inches

Table 1 – Device Comparison		
	Guardian Neonate CPAP / Humidification System (K040862)	**NeoPAP System**
	prongs or mask	upstream from patient.
Relief Valve Opening Pressure (Measured at Patient)	18 cmH_2O	15 cmH_2O
Nasal Cannula Sizes	Extra large, large, medium, small, and extra small.	Unchanged from K040862.
Nasal Mask Sizes	Large and small.	Unchanged from K040862.
Bonnet Design	Cotton bonnet without mechanism to adjust fit of bonnet. Laces thread through bonnet eyelets to secure patient interface.	Foam bonnet with hook and loop mechanism to adjust fit of bonnet. Adjustable bonnet clips to secure patient interface.
Bonnet Sizes	Sizes 0 to 11.	Extra large, large, medium, small, and extra small.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Children's Medical Ventures, LLC
C/O Mr. Scott Wright
Senior Regulatory Affairs Engineer
191 Wyngate Drive
Monroeville, Pennsylvania 15146

MAR 30 2011

Re: K103410
Trade/Device Name: NeoPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 18, 2011
Received: March 23, 2011

Dear Mr. Wright:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___NeoPAP System_

Indications for Use:

The NeoPAP System is intended to provide continuous positive airway pressure (CPAP) for use in hospitals to treat newborns and infants, weighing less than 5 kg, with RDS or who are recovering from RDS. (Respiratory Distress Syndrome).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103470