K082113

■Nox Medical■
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510(k) Summary

Submitter

NOV - 7 2008

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Registration Number: Nox Medical will register following FDA clearance

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Preparation Date

July 25, 2008

Device

Trade Name:	Nox T3
Common Name:	Sleep Recorder
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR
Device Class:	Class II
Classification Panel:	Anesthesiology

Predicate Devices

Embla N7000 from Medcare Flaga
Product Code: MNR
510(k) Number: K024322

Compass M10 from Medcare Flaga
Product Code: MNR
510(k) Number: K041724

4100 Patient Oximeter Module from Nonin Medical Inc.
Product Code: DQA
510(k) Number: K043359

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Device Description

The Nox T3 is an ambulatory recording system. It includes a recording device, respiratory effort sensors, clip straps, filter tube connector and an USB cable for data download and the Nox T3 application (Noxturnal).

The Nox T3 device is a pocket size battery powered digital recorder that incorporates electronics to record and store up to three nights of physiological parameters. The Nox T3 device is worn on the patient's chest by snapping it to the thoracic respiratory effort sensor belt and securing its position with the clip straps. It has a display for status indication, signal integrity and preliminary results, and buttons for control.

The Nox T3 device records signals from five external sensors and three built-in sensors. The external sensors that can be used with the device are abdominal and thoracic respiratory effort sensors, oximeter (via wireless transmission), and two leads of the following: ECG, EMG, EEG or EOG. The built-in sensors include a pressure transducer allowing either recording of nasal pressure (via nasal cannula) or mask pressure and measuring of snoring, a three dimensional acceleration sensor for measure of patient's position and activity, and a microphone for true audio recording capabilities.

The Nox T3 device includes a class II Bluetooth transmitter/receiver to allow for wireless transmission of data from Nonin´s Model 4100 Patient Oximeter Module.

The Nox T3 application (Noxturnal) is used to configure the device for recording, and downloading, viewing and analyzing of recorded data on a PC.

Intended Use

The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed and analyzed by use of the Nox T3 application (Noxturnal). The Nox T3 system is indicated for use in patients greater than 2 years of age.

The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.

The Nox T3 system is used for patients suspected of suffering from Sleep Disordered Breathing (SDB) or Periodic Limb Movement Disorder (PLMD).

Technological Characteristics

The comparison table below is provided as a summary of the most relevant characteristics of the Nox T3 system relative to the predicate devices. The comparison table demonstrates that the Nox T3 system has no significant differences from the predicate devices for the intended use that would adversely affect product safety and effectiveness.

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Table 1 Substantial Equivalence Summary

Characteristic	Embla N7000 (K024322)	Compass M10 System (K962865)	4100 Patient Oximeter Module (K043359)	Nox T3 System
General				
Intended Use	The Embla N7000 is intended for use by a physician or trained technician for the acquisition of EEG and polysomnography (PSG) signals and transmission of these signals to a PC during neurophysiologic or sleep examinations.	The intended use of the Compass M10 system is to record physiological signals during sleep, scan the signals for abnormalities and represent the count of abnormal events in a form of a summary report. The results of the scan may be manually overwritten or corrected by the physician. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's count of abnormal events. It is not intended for any diagnosis. It is not intended to be a monitor.	The Nonin's Bluetooth® enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible Bluetooth® enabled device.	The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed and analyzed by use of the Nox T3 application (Noxturnal). The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis.
Intended Environments	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.	Not defined	Not defined	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.
Patient Population	Not defined	The Compass M10 system is intended to be used for adult and pediatric patients.	Not defined	The Nox T3 system is indicated for use in patients greater than 2 years of age.
Prescription Use	Yes	Yes	Yes	Yes
Standards/Listing/Registrations				
IEC60601-1:1988	Yes	Yes	Yes	Yes
IEC60601-1-2:2001	Yes	Yes	Yes	Yes
IEC 60601-2-25:1993	Yes	NA	NA	Yes
IEC 60601-2-26: 2002	Yes (1994 version)	NA	NA	Yes
IEC 60601-2-40: 1998	Yes	NA	NA	Yes

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Characteristic	Embla N7000 (K024322)	Compass M10 System (K962865)	4100 Patient Oximeter Module (K043359)	Nox T3 System
47 CFR Part 15	NA	NA	Yes	Yes
FCC registration	NA	NA	Yes	Yes
Bluetooth EPL	NA	NA	Yes	Yes
		Physical		
Case Material	ABS Plastic (Patient Unit)	ABS Plastic and Aluminum	NA	ABS Plastic
RIP Belts Material	Polyester, latex free	Polyester, latex free	NA	Polyester, latex free
Dimension	80mm (2.5") W 111mm (4.9") H 18.5mm(0.8") D (Patient Unit)	65mm (2.5") W 124mm (4.9") H 20mm(0.8") D	NA	79mm (3.11") W 63mm (2.48")H 21mm(0.83") D
Weight	280g (Patient Unit)	100g	NA	65g
Disposable Components	Disposable respiratory effort sensor/RIP belts. Nasal cannula Remaining components require cleaning.	Disposable respiratory effort sensor/RIP belts. Remaining components require cleaning.	NA	Disposable respiratory effort sensor/RIP belts. Filter tube connector Remaining components require cleaning.
		Functional		
Acquisition units	Three units	One unit	NA	One unit
Number of channels	Seven channels (Patient Unit). 40 channels (Bedside Unit). Eight auxiliary channels (Communication Unit).	Five channels.	NA	Eight channels.
Recording time	Unlimited	Up to 12 hours	NA	Up to 24 hours
Control	Data acquisition and data storage microprocessor controlled Acquisition parameters set from application SW	Data acquisition and data storage microprocessor controlled Acquisition parameters set from application SW	NA	Data acquisition and data storage microprocessor controlled Acquisition parameters set from application SW
Device Data Storage	No	Yes	NA	Yes

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Characteristic	Embla N7000 (K024322)	Compass M10 System (K962865)	4100 Patient Oximeter Module (K043359)	Nox T3 System
Data Interface (PC)	Ethernet	USB v1.1	NA	USB v2.0
Connection to Patient	RIP belts for respiratory effort Probes or Flexi Wrap for oximetry Plastic tubing and cannula for pressure sensing Touch proof electrode cables Thermistor Snore Sensor Piezo belts for respiratory effort Elastic cloth material for support of device	RIP belts for respiratory effort Probes or Flexi Wrap for oximetry Elastic cloth material for support of device	NA	RIP belts for respiratory effort Probes or Flexi Wrap for oximetry Plastic tubing and cannula for pressure sensing Touch proof electrode cables RIP belts for attaching of device and clip straps to secure position of device
Signals and Sensors				
Signals recorded	Respiratory Effort (Abdomen and Thorax) Body position Activity Oxygen Saturation Pulse Nasal/mask pressure Airflow Snore Respiratory sound EEG, EOG, EMG, ECG	Respiratory Effort (Abdomen and Thorax) Body position Activity Oxygen Saturation Pulse	NA	Respiratory Effort (Abdomen and Thorax) Body position Activity Oxygen Saturation Pulse Nasal/mask pressure Airflow Snore Respiratory sound EEG, EOG, EMG, ECG
Sensor Technology used In/with the system	Solid state pressure sensor Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Oximetry	Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Oximetry	NA	Solid state pressure sensor Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Oximetry

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Characteristic	Embla N7000 (K024322)	Compass M10 System (K962865)	4100 Patient Oximeter Module (K043359)	Nox T3 System
	Microphone Gold cup electrodes Ag/AgCL electrodes Piezobelts for respiratory effort Thermistor Piezo snoring sensor			Microphone Gold cup electrodes Ag/AgCL electrodes
Power and Isolation				
Power Source	115/230V AC	3V by 2 AA batteries (Data Acquisition) Host PC (Data Transfer)	Two 1.5V AA batteries	1.5V by 1 AA battery (Data Acquisition) Host PC (Data Transfer)
Patient isolation	Isolation between mains and applied part	Device has no galvanic connections to mains as it is a battery operated device Not possible to connect auxiliary devices to the device	Device has no galvanic connections to mains as it is a battery operated device Not possible to connect auxiliary devices to the device	Device has no galvanic connections to mains as it is a battery operated device Not possible to connect auxiliary devices to the device
Transmitter				
RF Data Transfer	No	No	Bluetooth wireless technology	Bluetooth wireless technology
Bluetooth Specification	NA	NA	Version 1.1	Version 2.0
RF Operating frequency	NA	NA	2.4-2.4835 GHz	2.4-2.4835 GHz
RF Emissions CISPR 11	NA	NA	Group 2 Class B	Group 2 Class B
Output power	NA	NA	<1.1mW (Class II)	< 1.62mW (Class II)
Antenna Type	NA	NA	Internal	Internal
Modulation Type	NA	NA	Frequency Shift Keying Frequency Hopping Spread Spectrum	Frequency Shift Keying Frequency Hopping Spread Spectrum
Network Topology	NA	NA	Point-to-Point:	Point-to-Point:
Bandwidth	NA	NA	1 MHz	1 MHz
User Interface				

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Characteristic	Embla N7000 (K024322)	Compass M10 System (K962865)	4100 Patient Oximeter Module (K043359)	Nox T3 System
Data validation	On-line in the application SW (not a part of the system). Status light on Bedside Unit	Visual verification of the respiratory signals by light indicators on device	Connection status LED	The device has a display to view signal integrity and operation of the device.
Operating System	No PC application	Microsoft Windows™ 2000 and XP	NA	Microsoft Windows™ 2000 and XP
Data review on PC	No PC application	Yes: Real-time waveforms	NA	Yes: Real-time waveforms
Generate/Print reports	No PC application	Yes	NA	Yes
Patient data entry	No PC application	Yes	NA	Yes
Analysis	No PC application	Automatic, result may be manipulated. Manual analysis Event marking (scoring)	NA	Automatic, result may be manipulated. Manual analysis Event marking (scoring)

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Performance Testing Summary

The Nox T3 system has been tested and verified in various phases to include internal testing, verification and validation as well as external testing to assure product safety, effectiveness and reliability.

The design was verified and validated throughout the design process according to requirement specifications and intended use. Risk analysis was performed according to ISO 14971:2007, appropriate measures were implemented and their effectiveness verified and validated.

External test house was used to conduct testing needed to comply with applicable standards regarding EMC and patient safety as well as additional RF testing to assure compliance to FCC regulations and requirements for R&TTE (The Radio and Telecommunications Terminal Equipment Directive) approval.

The general process from configuration of device to reading out the results and generating report was validated by having untrained person perform this actions. The results demonstrates that the Nox T3 system has meet its objective of being easy to operate, the Noxturnal interface guides the user appropriately, minimizing the likelihood of errors and lapses, and the design of the Nox T3 components and user instruction allows the hook-up to be performed by untrained people.

Performance Data

The signals recorded with the Nox T3 system were compared to signals recorded with the predicate device Embla N7000. The result demonstrates the reliability and usability of all signals recorded with the Nox T3 system.

Analysis comparison was performed to validate the quality of the automatic scoring performed by the Noxturnal application compared to manual scoring of full PSG data. The validation study focused on the comparison of the Apnea Hypopnea Index (AHI) values and the Oxygen Desaturation Index (ODI) values. The recordings used consisted of 1057 Embla N7000 recordings which had all gone through the process of being manually scored by Sleep Technicians with RPSGT certification, and then reviewed by a Physician.

The analysis comparison result demonstrates that the Noxturnal application scores AHI and ODI events in a substantially equivalent manner to the manual scoring on full PSG recordings obtained using Embla N7000 recorders.

Conclusion

Verification testing, validation, risk analysis, technological characteristic and performance data comparisons have been performed for the Nox T3 system. The results of this testing and comparisons do not raise new questions of safety and effectiveness and demonstrate the same effectiveness and safety as that of the predicates Compass M10, Embla N7000 and Model 4100 Patient Oximeter Module.

The Nox T3 system is therefore substantial equivalent to the predicates Compass M10 from Medcare Flaga (K041724) and Embla N7000 from Medcare Flaga (K024322).

The wireless function of the Nox T3 system is therefore substantial equivalent to that of the predicate Model 4100 Patient Oximeter Module from Nonin Medical (K043359).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

Ms. Kolbrun E. Ottosdottir
Quality Manager
Nox Medical
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IS 112 Reykjavik
ICELAND

Re: K082113
Trade/Device Name: Nox T3
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 20, 2008
Received: October 23, 2008

Dear Ms. Ottosdottir:

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.

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) 276-0115. 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anita Y. McCain MS
FOR DR CHIU LIN

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K082113

Device Name: Nox T3

Indications For Use:

The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed and analyzed by use of the Nox T3 application (Noxturnal). The Nox T3 system is indicated for use in patients greater than 2 years of age.

The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.

Prescription Use _____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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, Dental Devices

510(k) Number: K082113