K124062

510(k) Summary

JUL 10 2013

Submitter

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Preparation Date

December 24, 2012

Device

Trade Name:	QDC-PRO
Common Name:	Respiratory Sensor Unit
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR
Device Class:	Class II
Classification Panel:	Anesthesiology

Predicate Devices

NOX T3 from Nox Medical
Product Code: MNR
510(k) Number: K082113

Respitrace QDC from SensorMedics Corporation
Product Code: BZQ
510(k) Number: K903011

Device Description

The QDC-PRO device is intended to function as an accessory for 3rd party PSG systems, delivering the respiratory signals needed in PSG studies along with position/activity signals.

Polysomnography (PSG) is a multi-parametric sleep study indicated for diagnosis of various sleep disorders. The QDC-PRO is therefore a part of a full PSG, the gold standard sleep study, and its main objectives is to provide signals used for diagnoses of sleep disordered breathing (SDB).

The signals measured by the QDC-PRO are provided as analog signals to a general 3rd party PSG amplifier that has DC inputs with characteristics matching the QDC-PRO device signal output specifications.

The output signals include:

- Abdomen respiratory effort (RIP)
- Thorax respiratory effort (RIP)
- SUM of abdomen and thorax respiratory effort (RIP)
- Nasal pressure from nasal cannula
- Snore signal from nasal cannula
- Body position
- Activity
- Audio

The respiratory effort is measured by the use of respiratory inductive plethysmography (RIP).

The QDC-PRO device provides calibration for the RIP signals by the use of Quantitative Diagnostic Calibration (QDC) technique. The calibrated RIP signals (Sum) represents the tidal volume of the respiration better than un-calibrated RIP signals.

The QDC-PRO contains a sensor unit, respiratory effort sensors (RIP belts) and cables. The QDC-PRO is worn by the patient. It measures signals from two respiratory effort sensors, audio via an inbuilt microphone, nasal pressure and snoring via a nasal cannula and patient's position/activity data. The signals are processed within the device and the resulting signals made available at the output connector for acquisition by a 3rd party polysomnography (PSG)/sleep recorder.

The QDC-PRO is powered with one AA (1.5V) battery and has a display for status indication, signal integrity, and buttons for control.

Intended Use

The QDC-PRO device is a sensor unit intended for measuring of physiological signals during sleep. The signals measured are processed in the QDC-PRO device and the resulting signals made available at the output connector for acquisition by a 3rd party polysomnography (PSG)/sleep recorder.

The QDC-PRO device is indicated for use in patients greater than 2 years of age.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

Technological Characteristics

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

Table 1 Comparison Summary of the New Device (QDC-PRO) and Predicate Devices

Characteristic	NOX T3 (K082113)	RESPITRACE QDC (K903011)	QDC - PRO
General			
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 RESPITRACE QDC multi-channel waveform generator is indicated for diagnostic polysomnograpy. This device generates respiratory waveforms from RESPITRACE technology.	The QDC-PRO device is a sensor unit intended for measuring of physiological signals during sleep. The signals measured are processed in the QDC-PRO device and the resulting signals made available at the output connector for acquisition by a 3rd party Polysomnography (PSG)/sleep recorder.
Contraindication for Use	The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis.	Not defined in labeling	The QDC-PRO device is NOT intended for any patient monitoring.
Intended Environments	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.	Not defined in labeling	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.
Patient Population	The Nox T3 system is indicated for use in patients greater than 2 years of age	Not defined in labeling	The QDC-PRO device is indicated for use in patients greater than 2 years of age.
Prescription Use	Yes	Yes	Yes
Physical/Material			
Material Case	ABS/PC	Painted metal housing	PC with 10% glass fiber
Material Device Clips	Polyester/Steel	Not defined in labeling	Polyester/Steel
Material RIP connection cable	PVC and ABS/PC	Not defined in labeling	PVC and ABS/PC
RIP Belts Material	Polyester/Dorlastan, latex free	Not defined in labeling	Polyester/Dorlastan, latex free
Dimension	79mm (3.11") W 63mm (2.48")H 21mm(0.83") D	195mm (76.8") W 275mm (108.3") H 110mm(43.3") D	83mm (3.27") W 63mm (2.48")H 21mm(0.83") D
Weight	65g	2000g	71g
Disposable Components	Disposable respiratory effort sensor/RIP belts. Filter tube connector Remaining portions require cleaning.	Disposable respiratory effort sensor/RIP belts. Remaining components require cleaning.	Disposable respiratory effort sensor/RIP belts. Remaining portions require cleaning.
Acquisition units	One unit	One unit	One unit
Functional			
Number of channels	Eight channels.	Three channels.	Eight channels.

Characteristic	NOX T3 (K082113)	RESPITRACE QDC (K903011)	QDC - PRO
Operation time	24 hours (depending on batteries)	Undefined (mains operated)	8 hours or longer (depending on batteries)
Data Acquisition Control	Data acquisition microprocessor controlled	Not defined in labeling	Data acquisition microprocessor controlled
Acquisition parameter Control	Acquisition parameters set from application SW	Acquisition parameters controlled from the device software only	Acquisition parameters controlled from the device software only
Calibration of RIP	No	Yes	Yes
Device Data Storage	Yes	No	No
Data Interface	Via USB connection to PC	Via analog interface to 3rd party sleep system Via serial port to PC	Via analog interface to 3rd party sleep system
Firmware upgrade	Via USB connection to PC	Not defined in labeling	Via USB connection to PC
Connection to Patient	RIP belts for respiratory effort RIP belts for attaching of device and clip straps to secure position of device Plastic tubing and cannula for pressure measurement Probes or Flexi Wrap for oximetry Touch proof electrode cables	RIP belts for respiratory effort	RIP belts for respiratory effort RIP belts for attaching of device and clip straps to secure position of device Cannula for pressure measurement
Signals and Sensors			

Characteristic	NOX T3 (K082113)	RESPITRACE QDC (K903011)	QDC - PRO
Signals outputs	Respiratory Effort (Abdomen and Thorax) RIP SUM Body position Activity Nasal /mask pressure Airflow Snore Respiratory sound/audio Oxygen Saturation Pulse EEG, EOG, EMG, ECG	Respiratory Effort (Abdomen and Thorax) – calibrated RIP SUM	Respiratory Effort (Abdomen and Thorax) – calibrated RIP SUM Body position Activity Nasal pressure Snore Respiratory sound /Audio intensity
Sensor Technology used in/with the system	Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Microphone Solid state pressure sensor Oximetry Gold cup electrodes Ag/AgCL electrodes	Respiratory Effort Sensors (RIP technology)	Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Microphone Solid state pressure sensor
Power and Isolation			
Power Source	1.5V by 1 AA battery (Data Acquisition) Host PC (Data Transfer)	115/230V AC (Data Acquisition)	1.5V by 1 AA battery (Data Acquisition) Host PC (FW upgrade)
Galvanic Connection to mains/Patient Isolation	Device has no galvanic connections to mains as it is a battery operated device Not possible to connect auxiliary devices to the device	Yes via connection over mains operated 3rd party amplifier Isolation between mains and applied part Via isolation mains adapter (mains operated)	Yes via connection over mains operated 3rd party amplifier Isolation between mains and applied part
User Interface			
Data validation	The device has a display to view signal integrity and status of the device	No	The device has a display to view signal integrity and status of the device
Control on device	Push buttons	On/off button	Push buttons
Standards			
IEC60601-1 or equivalent FDA recognized standard	Yes	Yes	Yes
IEC60601-1-2 or equivalent FDA recognized standard	Yes	Yes	Yes

Performance Testing Summary

Thorough internal and external testing has demonstrated that the QDC-PRO device is effective and safe for its intended use.

The QDC-PRO device complies with the applicable EMC and patient safety standards:

- IEC60601-1:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

- AAMI/ ANSI ES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1).

The software in the QDC-PRO device was developed in compliance with the requirements listed in the standard: IEC62304 - Medical Device Software - Software Life Cycle Processes, which provides a framework of life cycle processes with activities and tasks necessary for the safe design and maintenance of medical device software, including testing, verification and validation.

The design of the QDC-PRO device was tested, verified and validated throughout the design process according to requirement specifications and intended use.

Risk analysis was performed according to the standard: ISO14971 - Medical devices — Application of risk management to medical devices, appropriate measures was implemented and their effectiveness verified and validated.

Signal comparison tests conducted for the QDC-PRO device confirm the quality of the signals being measured by the device. The results demonstrate that the QDC-PRO signals may be regarded as clinically equivalent to that of the predicates Respitrace QDC and NOX T3.

Quantitative Diagnostic Calibration (QDC) function comparison tests conclude that the QDC-PRO performance may be regarded as clinically equivalent to that of the predicate Respitrace QDC.

Usability testing compliant with the standard: IEC 62366 - Medical devices – Application of usability engineering to medical devices, demonstrates that the QDC-PRO device is simple and safe to operate and minimizes the likelihood of errors and lapses.

Clinical evaluation for the QDC-PRO device concludes that all of the signals measured and processed by the device are comparable to the already validated and publicly available Respitrace QDC and Nox T3 device, respectively.

Conclusion

Based on the testing, risk analysis, verification and validation activates described above and detailed comparison to the predicate devices provided in Table 1 above, it is the conclusion of Nox Medical that the QDC-PRO device is substantially equivalent to the predicates NOX T3 from Nox Medical (K082113) and Respitrace QDC from SensorMedics Corporation (K903011) and presents no new concerns about safety and effectiveness.

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

July 10, 2013

Nox Medical
C/O Ms. Kolbrun E. Ottosdottir
Quality/Regulatory Manager
Katrinartuni 2
Reykjavik, Iceland IS-105

Re: K124062
Trade/Device Name: QDC-PRO
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: June 5, 2013
Received: June 10, 2013

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. 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.

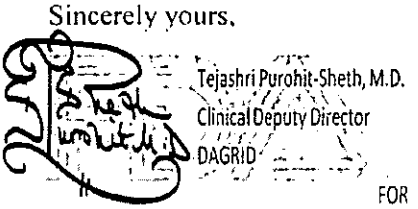
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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. 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

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K124062

Device Name: QDC-PRO

Indications For Use:

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The QDC-PRO device is indicated for use in patients greater than 2 years of age.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

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)

Anya C. Harry Digitally signed by Anya C. Harry
DN: c=US, g=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2018.07.09 16:24:57 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K124062