



Food and Drug Administration  
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November 6, 2015

Nox Medical ehf  
C/O Kolbrun E Ottosdottir  
Director of Quality & Regulatory  
Katrinarturni 2  
IS-105 Reykjavik  
ICELAND

Re: K151361

Trade/Device Name: Nox RIP Belts and Nox RIP Belt Cables  
Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing frequency monitor  
Regulatory Class: Class II  
Product Code: MNR  
Dated: October 2, 2015  
Received: October 5, 2015

Dear Mr. 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 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" (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 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
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Center for Devices and  
Radiological Health

Enclosure

# Indication for Use

510(k) Number (*if known*): K151361

Device Name: Nox RIP Belts

Indications for Use (Describe):

The Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems.

The Nox RIP Belts are indicated for use on patients greater than 2 years of age.

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

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Indication for Use

510(k) Number (*if known*): K151361

Device Name: RIP Belt Cables

Indications for Use (Describe):

The RIP Belt Cables are intended to interconnect Nox RIP belts (respiratory effort sensors) and Nox sleep devices, to allow measuring of respiratory effort signals.

The RIP Belt Cables are indicated for use on patients greater than 2 years of age.

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

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Indication for Use

510(k) Number (*if known*): K151361

Device Name: Third Party RIP Belt Cables

Indications for Use (Describe):

The Third Party RIP Belt Cables are intended to allow measuring of respiratory effort signals by interconnecting Nox RIP belts (respiratory effort sensors) and sleep devices with oscillation circuitry capable of measuring inductance between 1 and 5  $\mu$ H.

The Third Party RIP Belt Cables are indicated for use on patients greater than 2 years of age.

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

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 510(k) Summary

### Submitter

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Establishment Registration Number: 3007389703

### Contact person

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### Preparation Date

06 November 2015

### Device Details

Trade Name:	Nox RIP Belts	Nox RIP Belt Cables	
Product Groups		RIP Belt Cables	Third Party RIP Belt Cables
Common Name:	Respiratory Effort Sensor	Respiratory Effort Sensor	Respiratory Effort Sensor
Classification Name:	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Ventilatory Effort Recorder
Regulation Number:	868.2375	868.2375	868.2375
Product Code:	MNR	MNR	MNR
Device Class	Class II	Class II	Class II
Classification Panel:	Anesthesiology	Anesthesiology	Anesthesiology

## **Predicate Device**

QDC-PRO AND NOX-RIP from Nox Medical ehf  
Product Code: MNR  
510(k) Number: K124062

This predicate has not been subject to a design-related recall.

*Note1: Please note that the Nox RIP Belts will be regarded as a subsystem of the predicate, QDC-PRO AND NOX-RIP. The QDC-PRO AND NOX-RIP includes a recorder and several accessories but only the RIP belts will be addressed in the comparison between the new device and the predicate.*

*Note2: Please note that the Nox RIP Belt Cables will be regarded as a subsystem of the predicate, QDC-PRO AND NOX-RIP. The QDC-PRO AND NOX-RIP includes a recorder and several accessories but only the RIP belt cable will be addressed in the comparison between the new device and the predicate.*

## **Device Description**

The Nox RIP Belts are respiratory effort sensors that are intended to function as an accessory with sleep/polysomnography (PSG) systems. The RIP Belts measure respiratory effort signals based on Respiratory Inductance Plethysmography (RIP) technology, which is the gold standard technology for respiratory effort belts.

Two RIP belts are used to measure the respiratory effort of the patient. One belt is placed around the patient's abdomen and the other around the patient's thorax. Both abdomen and thorax belts are identical.

The Nox RIP Belt Cables are used to connect between the respiratory effort sensor (RIP belts) and the applicable sleep recorder/polysomnography (PSG) system.

There are two product groups for the Nox RIP Belt Cables; RIP Belt Cables and Third Party RIP Belt Cables.

The RIP Belt Cables are designed for use with Nox recorders only. Those are abdomen cables only because the thorax belt is attached directly to the Nox recorders.

The Third Party RIP Belt Cables are designed for use with third party recorders. The Third Party RIP Belt Cables come in pairs for abdomen and thorax.

## **Intended Use**

### ***Nox RIP Belts***

The Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems.

The Nox RIP Belts are indicated for use on patients greater than 2 years of age.

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

### ***RIP Belt Cables***

The RIP Belt Cables are intended to interconnect Nox RIP belts (respiratory effort sensors) and Nox sleep devices, to allow measuring of respiratory effort signals.

The RIP Belt Cables are indicated for use on patients greater than 2 years of age.

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

### ***Third Party RIP Belt Cables***

The Third Party RIP Belt Cables are intended to allow measuring of respiratory effort signals by interconnecting Nox RIP belts (respiratory effort sensors) and sleep devices with oscillation circuitry capable of measuring inductance between 1 and 5  $\mu\text{H}$ .

The Third Party RIP Belt Cables are indicated for use on patients greater than 2 years of age.

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

## **Technological Characteristics and Comparison with Predicate**

### ***Nox RIP Belts***

The comparison table below is provided as a summary of the intended use and most relevant characteristics of the Nox RIP Belts relative to the predicate device.

Please note that the Nox RIP Belts will be regarded as a subsystem of the predicate, QDC-PRO AND NOX-RIP. The QDC-PRO AND NOX-RIP includes a recorder and several accessories but only the RIP belts will be addressed in the comparison between the new device and the predicate.

Table 1 Comparison Summary of the New Device (Nox RIP Belts) and Predicate Device

Characteristic	QDC – PRO AND NOX-RIP (K124062)	Nox RIP Belts	Comparison Result
<b>General</b>			
<b>Intended Use</b>	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 third party Polysomnography (PSG)/sleep recorder.	The Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems.	Equivalent See Note 1 below
<b>Intended Environments</b>	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	Equivalent See Note 2 below
<b>Patient Population</b>	The QDC-PRO AND NOX-RIP are indicated for use in patients greater than 2 years of age.	The Nox RIP Belts are indicated for use on patients greater than 2 years of age.	Identical
<b>Prescription Use</b>	Yes	Yes	Identical
<b>Type of Modules</b>	RIP belts are disposable	RIP belts are disposable	Identical
<b>Various Belt Sizes</b>	Yes	Yes	Identical
<b>Physical/Material</b>			
<b>RIP Belts Material</b>	Elastic: Polyester/Dorlastan (not made with natural rubber latex), tin plated copper wire  Connector: ABS plastic	Elastic: Polyester/Dorlastan (not made with natural rubber latex), tin plated copper wire  Connector: ABS plastic	Identical
<b>Disposable Components</b>	Disposable respiratory effort sensor/RIP belts.	Disposable respiratory effort sensor/RIP belts.	Identical
<b>Functional</b>			
<b>Connection to Patient</b>	RIP Belts are attached to patient	RIP Belts are attached to patient	Identical
<b>Type of Equipment to Be Connected to</b>	Sleep recorder and RIP Belt Cable	Sleep recorder and RIP Belt Cable	Identical
<b>Connector Type</b>	RIP belts have connector for to connect to Nox proprietary RIP snaps	RIP belts have connector for to connect to Nox proprietary RIP snaps	Identical
<b>Signals and Sensors</b>			

<b>Signals Measured</b>	Respiratory Effort (Abdomen and Thorax)	Respiratory Effort (Abdomen and Thorax)	Identical
<b>Respiratory Effort Technology</b>	RIP (Respiratory Inductive Plethysmography) technology	RIP (Respiratory Inductive Plethysmography) technology	Identical
<b>Signal Processing</b>	No signal processing is done in RIP Belts	No signal processing is done in RIP Belts	Identical
<b>Power and Isolation</b>			
<b>Power Source</b>	No power source. RIP Belts contain only passive components	No power source. RIP Belts contain only passive components	Identical
<b>Isolation</b>	No component included in the RIP Belts that are relied on as means of protection	No component included in the RIP Belts that are relied on as means of protection	Identical
<b>Standards</b>			
<b>AAMI/ANSI/ES 60601-1</b>	Yes	Yes	Identical
<b>IEC 60601-1-2</b>	Yes	Yes	Identical

Note 1: Nox RIP Belts are intended for measuring of respiratory effort signals and function as accessories for sleep systems. The predicate, QDC-PRO AND NOX RIP, is intended for measuring of physiological signals during sleep. Respiratory effort is one example of physiological signals and both the new device and the predicate measure the signals during sleep. Furthermore, the predicate RIP belts are intended for measuring respiratory effort signals as an accessory to the QDC-PRO recorder. Therefore the indication for use can be regarded the same.

Note 2: The intended environment depends on the classification of the sleep recorder to be used with the Nox RIP Belts. The predicate device, QDC-PRO AND NOX-RIP, is intended to be used with a third party polysomnography (PSG) recorder. PSG studies are rarely performed in home environment and therefore it is not listed in the intended environments for the predicate. Simpler sleep recorders like polygraph (PG) recorders are commonly used at patients' home. The Nox RIP Belts may be used with any type of sleep recorders/PSG recorders including PG recorders. Therefore, the home environment was added for the Nox RIP Belts. If a sleep recorder is intended for home use, the type of RIP Belts does not change or influence the intended environment of the recorder. The home inclusion to the environment of use does therefore not pose any new safety and effectiveness concerns for the Nox RIP Belts. Additionally, risk analysis, verification and validation results demonstrate that the use of Nox RIP Belts in the home environment does not raise any new concerns regarding the intended use, safety or efficiency. Furthermore, these are prescription devices and are always used under supervision of a licensed medical practitioner. The intended environments are therefore deemed equivalent.

The result of the above comparison is that the indication for use, patient population and intended environments for the Nox RIP Belts can be regarded the same as that of the predicate QDC-PRO AND NOX-RIP device.

The comparison above demonstrates that all major technological characteristics, including features, materials, and principles of operation of the Nox RIP Belts are identical to the predicate QDC-PRO AND NOX RIP.

***Nox RIP Belt Cables***

The comparison table below is provided as a summary of the intended use and most relevant characteristics of the Nox RIP Belt Cables relative to the predicate device.

Please note that the Nox RIP Belt Cables will be regarded as a subsystem of the predicate, QDC-PRO AND NOX-RIP. The QDC-PRO AND NOX-RIP includes a recorder and several accessories but only the RIP belt cable will be addressed in the comparison between the new device and the predicate.

Table 2 Comparison Summary of the New Device (Nox RIP Belt Cables) and Predicate Device

Characteristic	QDC – PRO AND NOX-RIP (K124062)	Nox RIP Belt Cables		Comparison Results
		RIP Belt Cables	Third Party RIP Belt Cables	
<b>General</b>				
<b>Intended Use</b>	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 third party Polysomnography (PSG)/sleep recorder.	The RIP Belt Cables are intended to interconnect Nox RIP belts (respiratory effort sensors) and Nox sleep devices, to allow measuring of respiratory effort signals.	The Third Party RIP Belt Cables are intended to allow measuring of respiratory effort signals by interconnecting Nox RIP belts (respiratory effort sensors) and sleep devices with oscillation circuitry capable of measuring inductance between 1 and 5 µH.	Equivalent  See Note 3 below
<b>Intended Environments</b>	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	Equivalent  See Note 4 below
<b>Patient Population</b>	The QDC-PRO AND NOX-RIP are indicated for use in patients greater than 2 years of age.	The RIP Belt Cables are indicated for use on patients greater than 2 years of age.	The Third Party RIP Belt Cables are indicated for use on patients greater than 2 years of age.	Identical
<b>Prescription Use</b>	Yes	Yes	Yes	Identical
<b>Type of Modules</b>	RIP Belt Cable for connection to recorder and RIP belts	RIP Belt Cable for connection to recorder and RIP belts	RIP Belt Cables for connection to recorder and RIP belts	Identical
<b>Physical/Material</b>				
<b>RIP Cables Material</b>	<ul style="list-style-type: none"> <li>• PVC – wire jacket</li> <li>• PC with 10% glass fiber – belt end</li> <li>• PC with 10% glass fiber – device end</li> <li>• Gold plated stainless steel – snaps</li> <li>• TPE – strain relief</li> </ul>	<ul style="list-style-type: none"> <li>• PVC – wire jacket</li> <li>• ABS/PC – belt end</li> <li>• ABS/PC – device end</li> <li>• Gold plated stainless steel – snaps</li> <li>• TPE – strain relief</li> </ul>	<ul style="list-style-type: none"> <li>• PVC – wire jacket</li> <li>• ABS/PC – belts end</li> <li>• TPE-ET – device end strain relief</li> <li>• Gold plated stainless steel – snaps</li> <li>• TPE-ET – strain relief</li> </ul> <p>Note: TPE-ET is also known as Riteflex®</p>	Equivalent  See Note 5 below
<b>Disposable</b>	RIP Belt Cable is	RIP Belt Cable is	Third Party RIP Belt Cables	Identical

<b>Components</b>	reusable	reusable	are reusable	
<b>Functional</b>				
<b>Connection to Patient</b>	RIP Belt Cable is attached to patient via connection to RIP belts	RIP Belt Cable is attached to patient via connection to RIP belts	Third Party RIP Belt Cables are attached to patient via connection to RIP belts	Identical
<b>Type of Equipment to Be Connected to</b>	Interconnect sleep recorder and respiratory effort sensor (RIP belt)	Interconnect sleep recorder and respiratory effort sensor (RIP belt)	Interconnect sleep recorder and respiratory effort sensor (RIP belt)	Identical
<b>Belt Cable Connectors – Recorder End</b>	Proprietary connector for Nox RIP snaps	Proprietary connector for Nox RIP snaps	Touch proof 1 mm 2 pin female connector	Equivalent See Note 6 below
<b>Belt Cable Connectors – Belt End</b>	Gold coated proprietary metal snaps	Gold coated proprietary metal snaps	Gold coated proprietary metal snaps	Identical
<b>Signals and Sensors</b>				
<b>Signal Processing</b>	No signal processing done in RIP Belt Cable	No signal processing done in RIP Belt Cable	No signal processing done in Third Party RIP Belt Cables	Identical
<b>Power and Isolation</b>				
<b>Power Source</b>	No power source. RIP Belt Cable contains only passive components	No power source. RIP Belt Cable contains only passive components	No power source. Third Party RIP Belt Cables contain only passive components	Identical
<b>Isolation</b>	No component included in the RIP Belt Cable that is relied on as means of protection	No component included in the RIP Belt Cable that is relied on as means of protection	No component included in the Third Party RIP Belt Cables that is relied on as means of protection	Identical
<b>Standards</b>				
<b>AAMI/ANSI/ES 60601-1</b>	Yes	Yes	Yes	Identical
<b>IEC 60601-1-2</b>	Yes	Yes	Yes	Identical

Note 3: Nox RIP Belt Cables are intended to allow measuring of respiratory effort signals and function as accessories for sleep systems. The predicate, QDC-PRO AND NOX RIP, is intended for measuring of physiological signals during sleep. Respiratory effort is one example of physiological signals and both the new device and the predicate allow measuring of the signals during sleep. Furthermore, the predicate RIP belt cable is intended to interconnect RIP belts and the QDC-PRO recorder to allow measuring of respiratory effort signals. Therefore the indication for use can be regarded the same.

Note 4: The intended environment depends on the classification of the sleep recorder to be used with the Nox RIP Belt Cables. The predicate device, QDC-PRO AND NOX-RIP, is intended to be used with a third party polysomnography (PSG) recorder. Simpler sleep recorders like polygraph (PG) recorders are commonly used at patients' home. The Nox RIP Belt Cables may be used with any type of sleep recorders/PSG recorders including PG recorders. Therefore, the home environment was added for the Nox RIP Belt Cables. If a sleep recorder is intended for home use, the type of RIP belt cables does not change or influence the intended environment of the recorder. The home inclusion to the environment of use does therefore not pose any new safety and effectiveness concerns for the Nox RIP Belt Cables. Additionally, risk analysis, verification and validation results demonstrate that the use of Nox RIP Belt Cables in the home environment does not raise any new concerns regarding the intended use, safety or efficiency. Furthermore, these are prescription devices and are always used under supervision of a licensed medical practitioner. The intended environments are therefore deemed equivalent.

Note 5: The RIP Belt Cables and Third Party RIP Belt Cables are compliant to standard AAMI/ANSI ES/60601-1. Furthermore, verification testing and risk analysis show that minor difference in material does not raise new questions about safety and effectiveness. The material of the new devices and the predicate can thus be regarded as equivalent.

Note 6: All cables, both new and predicate, are compliant with standard AAMI/ANSI ES/60601-1. Furthermore, verification testing, signal integrity comparison and risk analysis show that different connectors do not raise new questions about safety and effectiveness. The recorder end connectors can thus be regarded as equivalent.

The result of the above comparison is that the indication for use, patient population and intended environments for the Nox RIP Belt Cables can be regarded the same as that of the predicate QDC-PRO AND NOX-RIP device.

Furthermore, the comparison above shows that there are no significant differences in major technological characteristics, including features, materials, and principles of operation of Nox RIP Belt Cables compared to the predicate. The minor differences between the new and predicate device do not raise any new questions regarding safety and effectiveness. It can therefore be determined that Nox RIP Belt Cables have the same major technological characteristics as the predicate device, QDC-PRO AND NOX RIP.

## **Performance Testing Summary**

Thorough internal testing has demonstrated that the Nox RIP Belts and Nox RIP Belt Cables are suitable for their intended use.

The design of the Nox RIP Belts and Nox RIP Belt Cables was tested, verified and validated throughout the design process according to product requirement specifications and intended use.

The Nox RIP Belts and Nox RIP Belt Cables comply with the following standards:

- ISO 14971 Second edition 2007, Medical devices – Application of risk management to medical devices
- ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
- AAMI/ANSI/ES 60601-1:2005, Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- AAMI/ANSI/IEC 62366:2007/(R)2013, Medical devices – Application of usability engineering to medical devices

Additionally, the Third Party RIP Belt Cables comply with

- 21 CFR 898 – FDA PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES:2014

### ***Verification***

Nox RIP Belts and Nox RIP Belt Cables were tested towards test protocols written to cover all product requirement specifications. The test results demonstrate that the design output conforms to design input and that the device fulfills all physical characteristics, performance criteria, functional requirements, environmental requirements, interface requirements, packaging and labeling requirements as well as safety and reliability requirements defined.

### ***Risk Analysis***

Risk analysis was performed for RIP Belts and RIP Belt Cables according to the standard: ISO 14971 - Medical devices - Application of risk management to medical devices, appropriate measures have been implemented and their effectiveness verified and validated.

### ***Standards Testing***

Assessment has been conducted for RIP Belts and RIP Belt Cables towards the standard AAMI/ANSI/ES 60601-1:2005. The result of this assessment is that the RIP Belts and RIP Belt Cables are in compliance with the standard AAMI/ANSI/ES 60601-1:2005.

### ***EMC Testing***

Assessment has been conducted for RIP Belts and RIP Belt Cables towards the electromagnetic compatibility standard IEC 60601-1-2 Edition 3: 2007-03 to ensure compatibility with requirements addressing electrostatic discharge (ESD), electromagnetic disturbances, magnetic fields, electrical fast transients and bursts, and surge. The result of this assessment is that the RIP Belts and RIP Belt Cables are in compliance with the standard IEC 60601-1-2 Edition 3: 2007-03.

### ***Usability***

The RIP Belts and RIP Belt Cables were designed to minimize use errors and use-associated risks according to the usability engineering standard AAMI/ANSI/IEC 62366:2007/(R)2013. Usability testing resulted in all usability goals passed.

### ***Signal Quality and Comparison Testing***

Signal integrity tests were conducted for the Nox RIP Belts and Nox RIP Belt Cables with focus on signal to noise ratio, signal range, bandwidth and linearity and the test results compared to the signal integrity test conducted for the predicate QDC-PRO AND NOX-RIP.

The results from these signal integrity tests and comparison demonstrate that the Nox RIP Belts and Nox RIP Belt Cables signals are clinically equivalent to that of the predicate QDC-PRO AND NOX RIP.

### **Conclusion**

Based on the testing, risk analysis and verification activities described above and detailed comparison to the predicate device provided in Table 1 and Table 2 above, it is the conclusion of Nox Medical that the Nox RIP Belts and Nox RIP Belt Cables are substantially equivalent to device already on the market (cleared by the 510(k) process) and present no new concerns about safety and effectiveness.

The Nox RIP Belts and Nox RIP Belt Cables are therefore substantial equivalent to the predicate QDC-PRO AND NOX-RIP from Nox Medical (K124062).