MAR 1 5 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

K 111933

A. SUBMITTER INFORMATION:

Submitter's Name:	Covidien
Address:	6135 Gunbarrel Avenue Boulder, CO 80301
Contact: Phone: Fax:	Jean Simon 303-305-2435 303-305-2212
Date of Preparation:	January 27, 2012

B. DEVICE NAME:

Trade Name(s):	Covidien Nellcor™ Respiration Rate Software, Version 1.0 and Covidien Nellcor™ Adult Respiratory Sensor
Common/Usual Name:	Respiration Rate Software, Version 1.0
Classification Names:	Class II, Anesthesiology
CFR Reference:	21 CFR 868.2375
Product Code:	BZQ, DSA

C. PREDICATE DEVICES:

CAS Medical	Model 750E (K051896)
Nellcor Puritan Bennett	Model N-600x (K083325)
Nellcor Puritan Bennett	Model MAX-A Sensor (K012891)

D. DEVICE DESCRIPTION:

The Covidien Nellcor™ Respiration Rate Software allows for the continuous non-invasive monitoring of arterial oxygen saturation (SpO2), pulse rate and respiration rate using a single sensor. The previously cleared Nellcor N-600x pulse oximeter collects the photoplethysmography signal from the patient via the Covidien Nellcor™ Adult Respiratory sensor attached to the patient. This signal is processed by the pulse oximeter to determine SpO2 and pulse rate. Data is then transmitted from the pulse oximeter to a medical grade PC via a data port.

The Respiration Rate Software (RRS) is installed on a medical-grade PC and utilizes data from the pulse oximeter to calculate respiration rate. The RRS also provides an

interactive user interface to display respiration rate, trending, system status and alarm information to the user. The RRS also allows for the collection and storage of data on the medical grade PC for subsequent export.

E. **INDICATIONS FOR USE:**

For Software:
The Covidien Nellcor™ Respiration Rate Software, when used in conjunction with a Nellcor pulse oximeter and a Nellcor Respiration Rate Sensor, is intended to be used for the continuous, non-invasive monitoring of respiration rate in adults in hospitals and hospital-type facilities.

For Sensor:
The Nellcor™ Adult Respiratory Sensor, when used in conjunction with a Nellcor pulse oximeter and the Nellcor Respiration Rate Software Application, is indicated for single patient use when continuous noninvasive arterial oxygen saturation, pulse rate and respiration rate monitoring are required for adult patients weighing more than 30 kg.

F. **TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:**

The subject device, the Covidien Nellcor™ Respiration Rate Software and the Covidien Nellcor™ Adult Respiratory Sensor, has the same intended use (Adults), general design (continuous, non-invasive indication of respiration rate) and fundamental scientific technology (indicator of central ventilatory drive) as the predicate device (K051896 and K012891) with respect to Respiration Rate.

The Respiration Rate Software uses photoplethysmography to calculate respiration rate and the predicate device uses impedence pneumography/Trans- thorasic Impedence (TTI), both of which are indicators of central ventilator drive. The respiration rate measurement range for the Respiration Rate Software is 4-40 breaths/minute, and is indicated for adults only. Both the subject and predicate devices have an accuracy of ±1 breaths/minute for the adult population.

G. **PERFORMANCE DATA SUMMARY:**

Non-clinical performance data summary-

The appropriate safety, environmental, performance and functional testing was conducted to ensure that the specifications of the Covidien Nellcor Respiration Rate Software and Covidien Nellcor™ Adult Respiratory Sensor were met.

Testing and evaluation was conducted according to the FDA Guidance documents and consensus standards shown below:

- "Use of Standards in Substantial Equivalence Determinations" – March 12, 2000
- "General principles of Software Validation, Final Guidance for Industry and FDA Staff", issued on January 11, 2002

- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: ICH Harmonized Tripartite Guideline: Guideline for Good Clinical Practice E6(R1)10 June 1996
- CEI/IEC 60601-1-8:2006, (Alarm systems in medical electrical equipment)
- EN IEC 60601-1-6:2004 (Usability)
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- ISO 11135-1:2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

The results of this testing demonstrate that the Covidien Nellcor™ Respiration Rate Software when used with the Covidien Nellcor™ Adult Respiratory Sensor has a respiration rate measurement range of 4-40 breaths per minute with an accuracy of ±1 breath per minute, and is substantially equivalent to the predicate device with respect to Respiration Rate (for adults).

Clinical Summary –

Clinical validation studies on healthy adult volunteers and on subjects from the hospital general care floor were conducted to assess the accuracy of the Respiration Rate Software algorithm. The studies demonstrated the accuracy of the Respiration Rate Software algorithm was as good at the predicate, transthoracic impendence measurements, when both were compared a gold standard. The studies demonstrated the Respiration Rate Software algorithm calculates respiration rate within a stated accuracy of ±1 breath per minute over a range of 4-40 breaths per minute and is shown to be substantially equivalent to the predicate device.

No device related adverse event were observed during the clinical studies.

H. Conclusions

The information provided in this 510(k) demonstrates the Respiration Rate Software when used in conjunction with the Adult Respiratory Sensor is substantially equivalent to the predicate device with respect to safety, effectiveness and performance.

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

Ms. Jean Simon
Senior Director, Regulatory Affairs
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

MAR 1 5 2012

Re: K111933
Trade/Device Name: Covidien Nellcor™ Respiration Rate Software, Version 1.0
Covidien Nellcor™ Adult Respiratory Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ, DQA & DSA
Dated: February 5, 2012
Received: March 6, 2012

Dear Ms. Simon:

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 D. 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

1.3 Indications for Use Statement

510(k) Number (if known): K111933

Device Name: Covidien Nellcor™ Respiration Rate Software, Version 1.0

Indications for Use:

The Covidien Nellcor™ Respiration Rate Software, when used in conjunction with a Nellcor pulse oximeter and a Nellcor Respiration Rate Sensor, is intended to be used for the continuous, non-invasive monitoring of respiration rate in adults in hospitals and hospital-type facilities.

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: K111933

1.3 Indications for Use Statement

510(k) Number (if known): K111933

Device Name: Covidien Nellcor™ Adult Respiratory Sensor

Indications for Use:

The Nellcor™ Adult Respiratory Sensor, when used in conjunction with a Nellcor pulse oximeter and the Nellcor Respiration Rate Software, is indicated for single patient use when continuous noninvasive arterial oxygen saturation, pulse rate and respiration rate monitoring are required for adult patients weighing more than 30 kg.

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

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CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

L Schultheiss

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

510(k) Number: K111933