K043132

Medcare

DEC 21 2004

510(k) Summary

Submitter

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Preparation Date

November 1st, 2004

Device

Trade Name:	Universal XactTrace
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR
Device Class:	Class II
Classification Panel:	Anesthesiology

Predicate Devices

Crystal Trace Piezo Respiratory Effort Sensor from Pro –Tech
Product Code: BZQ
510(k) Number: K923402

Summit IP from Compumedics USA
Product Code: MNR
510(k) Number: K040194

Device Description

The Universal XactTrace is a small battery powered reusable respiratory effort sensor. It incorporates electronics to measure and process a respiratory effort signal to provide an electrical signal suitable for connection to the inputs of a physiological recorder.

The Universal XactTrace is composed of a sensor belt and a belt cable. The sensor belt has two types: abdomen belt that is applied around the patient's abdomen and thorax belt that is applied around the patient's thorax. The sensor belts are intended to be worn over clothing. The belt cable is used to connect the belt sensor to a physiological recorder.

The Universal XactTrace is powered by a non replaceable battery that is built in the buckle of the sensor belt and switches on/off when the buckle is connected/unconnected.

The Universal XactTrace is based on Respiratory Inductive Plethysmograph (RIP) technique.

Intended Use

Universal XactTrace is intended to measure respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort signals measured are processed to provide electrical signals suitable for connection to the inputs of physiological recording equipment.

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

Universal XactTrace is intended for diagnostics purposes only and is not intended to be used as an apnea monitor.

Technological Characteristics

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. The summary demonstrates that the Universal XactTrace has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

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Table 1 Comparative Table

	Crystal Trace Piezo Respiratory Effort Sensor (K923402)	Summit IP (K040194)	Universal XactTrace
Modules	Abdomen and Thorax sensor belts.	Abdomen and Thorax sensor belts. Amplifying box a separate module.	Abdomen and Thorax sensor belts with in-build amplifier.
Equipment to be connected to	Physiological recorder.	Physiological recorder.	Physiological recorder.
Materials in contact with patient's skin	Velcro loop and elastic.	None. The sensor belts and bands should be worn over light clothing.	None. The sensor belts should be worn over light clothing.
Dimension of amplifying module	No amplifying module.	Patient Input Box: Height 21mm Width 41mm Length 59mm	Buckle of sensor belt: Height 13mm Width 42mm Length 55mm
Weight	Not specified.	Patient Input Box including battery but not sensor belt: 39g.	Total weight <60g.
Various Band/ Sensor belt sizes	Yes.	Yes.	Yes.
Belt cable connectors – recorder end	Bipolar touch proof safety connectors.	Among others: Bipolar touch proof safety connectors.	Bipolar touch proof safety connectors.
Power Source	No power source.	Replaceable battery: one N size (IEC-LR1) alkaline battery.	Non replaceable internal battery: 3.0V/1000mAh Type CR2477 Lithium Button Cell.
On/Off Control	N.A.	Connection/Disconnection of sensor belt to Patient Input Box.	Connection/Disconnection of Sensor Belt Buckle.
Battery consumption	N.A.	Approximately 800 hours operating time per battery.	2000 hours nominal operating time.
Indicators	No.	3 (red, amber, green) LEDs. Status of battery. Operation mode.	2 (yellow, green) LEDs. Status of battery.
Embedded Software	No.	Yes.	Yes.
Signal processing	No.	Yes.	Yes.
Patient safety	Not specified.	Conforms to IEC60601-1:1988+A1:1991+A2:1995.	Conforms to IEC60601-1:1988+A1:1991+A2:1995.

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	Crystal Trace Piezo Respiratory Effort Sensor (K923402)	Summit IP (K040194)	Universal XactTrace
Method of Connection to Patient	Sensor belts + Velcro bands are applied around thorax and abdomen.	Sensor belts + bands are applied around thorax and abdomen.	Sensor belts are applied around thorax and abdomen.
Single use	No part single use.	No part single use.	No part single use.
Signals measured	Abdominal and thoracic respiratory effort.	Abdominal and thoracic respiratory effort.	Abdominal and thoracic respiratory effort.
Signals output	Abdomen and thoracic respiratory effort.	Abdomen and thoracic respiratory effort. Sum.	Abdomen and thoracic respiratory effort.
Typical signal output size	Not specified.	1mVpp.	1.5mVpp.
Maximum signal amplitude	Not specified.	±5.0 mV.	±5.6 mV.
Frequency range output signal	Not specified.	0.05 to 5.0Hz.	0.05 to 5.0Hz.
Sensor Technology	Piezo material technology.	Respiratory Inductive Plethysmography (RIP) technique.	Respiratory Inductive Plethysmography (RIP) technique.
EMC compatibility	Not specified.	IEC60601-1-2:2001	IEC60601-1-2:2001.

Performance Testing

The Universal XactTrace has been tested and verified in various phases, internal testing and verification as well as external testing.

The design was verified throughout the design process. Hardware and firmware test specification were tested to ensure compliance to all design requirements.

Risk analysis was performed, appropriate measures were implemented and their effectiveness verified.

External test house, SEMKO, was used to confirm compliance to the following standards:

- IEC60601-1:1998 +A1:1991 and A2:1995 Medical Electrical Equipment, General Requirements for safety to ensure that there are no detrimental effects on patients, operators or the surrounding environment.

- IEC60601-1-2:.2001 Medical Electrical Equipment Part 1, General Requirements for safety 2. Collateral Standard: Electromagnetic compatibility – requirements and tests. These includes both emission tests to ensure that no intolerable electromagnetic disturbances are introduced to the environment and immunity tests to ensure safe and effective operation in the presence of electromagnetic interference.

Cables and leads confirm to CDRH Guidance Document on the "Performance Standard for Lead Wires and Patient Cables" March 9 1998.

Furthermore the signals detected with the Universal XactTrace were compared to signals detected with the predicate devices "Crystal Trace Piezo Respiratory Effort Sensor" and "Summit IP". The result demonstrates the reliability and usability of the abdominal and thoracic respiratory effort signals measured with the Universal XactTrace.

Conclusion

Based on the extensive testing, performance data and comparison to the predicate devices, it is the conclusion of Medcare Flaga that the Universal XactTrace is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Mr. Kolbrún Eydís Ottósdóttir
Regulatory Affairs
Medcare Flaga
Sidumuli 24
108 Reykjavik
Iceland
EUROPE

Re: K043132
Trade/Device Name: Universal XactTrace
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: November 1, 2004
Received: November 12, 2004

Dear Mr. Ottósdóttir:

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.

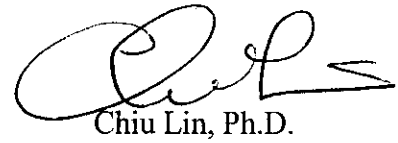
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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):

Device Name: Universal XactTrace

Indications For Use:

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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

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