K040194

APR 2 3 2004

SECTION 4. 510(k) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Limited summary for the Compumedics Summit IP.

SUBMITTER'S NAME:	Compumedics Limited
ADDRESS:	7850 Paseo del Norte El Paso, TX 79912 USA
CONTACT PERSON:	Elvira Garcia
TELEPHONE NUMBER:	915-225-0303
FAX NUMBER:	915-845-2965
DATE OF SUBMISSION:	January 22, 2004

1. **Identification of device**

Proprietary name:	Compumedics Summit IP
Common name:	respiratory effort module
Classification name:	Ventilatory Effort Recorder
Class:	Class II per regulations 868.2375
Product Code	MNR

2. **Predicate devices**

Compumedics Limited believes the Compumedics Summit IP is substantially equivalent to:

Device name:	Synchrony™ summing amplifier
Supplier:	Pro-Tech Services, Inc.
510(k) number:	K013905

The sensors used by the Summit IP are identical to those used by the respiratory effort part of the Compumedics Somté System.

Device name:	Compumedics Somté System
Supplier:	Compumedics Limited
510(k) number:	K021176

3. **Description of the Device**

The Compumedics Summit IP consists of a small plastic enclosure with two input sockets for connection to Compumedics respiratory effort bands (Thoracic and Abdominal), and output sockets for the Thoracic, Abdominal and Sum channels. The Sum channel is a weighted sum of the Thoracic and Abdominal signals. The output channels may be connected to the inputs of standard physiological equipment for the purpose of recording or monitoring respiratory effort.

The Summit IP is powered by a user-replaceable 1.5 volt battery and automatically switches on when any or both sensors are connected.

4. **Intended Use**

The Summit IP is intended for use in private practices or hospital environments for the detection of human respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. Signals from patient worn thoracic and abdominal sensors are demodulated, amplified and summed to provide electrical signals suitable for connection to the inputs of physiological recording equipment.

The Summit IP unit is only to be used under the direction and supervision of a physician.

The Summit IP unit is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Summit IP unit is not intended for use on infant or pediatric patients.

5. Technical characteristics, comparison to predicate device

COMPARATIVE TABLE

Characteristic	Compumedics Summit IP	Pro-Tech Synchrony™ Summing Amplifier
Intended Use	Intended for use during sleep disorder studies to acquire respiratory effort suitable for recording using a physiological recorder for diagnostic purposes.	same
Number of inputs	2	same
Sensor location	Around thorax and abdomen	same
Sensor type	Linear response to stretch	same
Output channels	3 (thoracic, abdominal, sum)	same (Qsum is name of sum channel)
Output connectors	1.5mm touch-proof safety connectors	same
Output Signal size, typical	1mVpp for all channels	0.6mVpp for thoracic and abdominal, 1.2mVpp for Qsum
Equipment outputs to be connected to	Physiological recorder	same
Physiological recorder high pass frequency	<0.3Hz	same
Physiological recorder low pass frequency	5Hz to 20 Hz	5Hz to 15Hz
Function of sum channel	To more easily identify thoracic and abdominal effort signals that are out of phase (paradoxical)	same
Power	Internal 1.5V alkaline battery, user replaceable	Internal 3.6V lithium battery, not user replaceable
Controls	None	One, cal switch
Indicators	3 (red, amber, green) LEDs	1 bicolor(red/green) LED
Indicator functions	Calibration, battery condition, operating status	Calibration, battery condition
Method of reducing battery consumption when not in use	Disconnection of sensors	same
Calibration initiation	Automatic after connection of both sensors	Press red "cal" button
Maximum calibration time	10 minutes	3 minutes
Calibrating indication	Fast Flashing Green LED	Green LED
Failed calibrating indication	Flashing Amber LED	Red LED
Purpose of calibration	Measure amplitudes of Thoracic and Abdominal signals to set mix of these signals used by Sum channel	Same
Operating indication	Slow flashing Green LED	none
Size, mm	59 L x 41 W x 21 H	70 L x 51 W x 20 H

NOTE
There is no comparative table for the respiratory effort sensors used in the Compumedics Somté System, K021176, as the sensors used by Summit IP are identical.

6. Discussion of performance testing

An extensive collection of tests has been conducted and successfully completed, including:

Safety tests to *IEC60601-1 (1988 +A1:1999+ A2:1995), Medical Electrical Equipment, General Requirements for safety*, to ensure there are no detrimental effects on patients, operators or the surrounding environment.

Electromagnetic emission tests to *IEC60601-1-2 (2001) Medical Electrical Equipment, General Requirements for safety, Collateral standard: Electromagnetic compatibility – requirements and tests*, to ensure no intolerable electromagnetic disturbances are introduced to the environment.

Electromagnetic immunity tests to IEC60601-1-2 to ensure safe and effective operation in the presence of electromagnetic interference.

Safety tests to U.S. and Canadian deviations from IEC60601-1.

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

Compliance tested to hardware and firmware test specifications to ensure conformance to all design requirements.

7. Conclusion

Based on extensive performance testing and comparison to the predicate device, it is the conclusion of Compumedics Limited that the Compumedics Summit IP 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

APR 2 3 2004

Ms. Elvira Garcia
Compumedics USA, LTD.
7850 Paseo Del Norte
El Paso, Texas 79912

Re: K040194
Trade Name: Compumedics Summit IP
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: March 31, 2004
Received: April 1, 2004

Dear Ms. Garcia:

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.

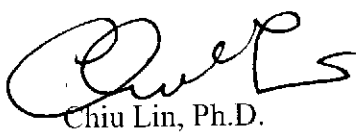
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-5613. 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

SECTION 3. STATEMENT OF INDICATION FOR USE

510(k) Number_____

Device Name: Compumedics Summit IP

Indications for use:

The Summit IP is intended for use in private practices or hospital environments for the detection of human respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. Signals from patient worn thoracic and abdominal sensors are demodulated, amplified and summed to provide electrical signals suitable for connection to the inputs of physiological recording equipment.

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(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___XX___ OR Over the Counter Use_____

(Per 21 CFR 801.109)

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

510(k) Number: K040194