K072201
page 1 of 5

APR 14 2008

4 510(k) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Pty Ltd summary for the SOMTÉ PSG SYSTEM.

SUBMITTER'S NAME:	Compumedics Pty Ltd
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	Abbotsford, Victoria, 3067
	Australia
CONTACT PERSON:	Gordon Ferguson
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DATE OF SUBMISSION:	3May07

1. Identification of device

Proprietary Name:	Compumedics Somté PSG System
Common Name:	SOMTÉ PSG SYSTEM
Classification Status:	Class II per regulations 868.2375
Product Codes:	MNR

2. Predicate devices

Compumedics Limited believes the SOMTÉ PSG SYSTEM is substantially equivalent to:

Device name:	Compumedics Sleep Monitoring System
Supplier:	Compumedics Limited
510(k) number:	K955841.
Device name:	Compumedics Somté Recording System
Supplier:	Compumedics Limited
510(k) number:	K021176.

3. Description of the Device

The Somté PSG System comprises hardware and software which provides up to 27 separate parameters for recording, review and analysis of collected and stored physiological parameters, including EEG, EOG, ECG and respiratory signals, which are then used as an aid in the diagnosis of respiratory and/or cardiac related sleep disorders by qualified physicians.

The Somté PSG device consists of two components permanently connected by a cable: the Patient Input Box (PIB) and the Recorder. The Somté PSG device is powered by 2 AA Batteries – Alkaline or NiMh.

4. Intended use

The Somté PSG is intended for use by or under the direction of physicians in private practices or hospital environments to assist in the diagnosis of various sleep disorders or sleep related respiratory or cardiac disorders.

5. Technological characteristics, comparison to predicate device.

COMPARATIVE TABLE

Characteristic	*Compumedics Somté PSG Recording System*	*Compumedics P-Series Sleep Monitoring System (predicate device)*	*Compumedics Somté Recording System (predicate device)*
Intended Use	Sleep/Respiratory recording and analysis, Ambulatory ECG recording and analysis	Sleep/Respiratory recording and analysis	Sleep/Respiratory recording and analysis, Ambulatory ECG recording and analysis
510(k) number		K955841	K021176
Environmental	5 to 45 deg C 20 to 90 % relative humidity less than 3000m altitude	0 to 45 deg C 30 to 95% relative humidity less than 3000m altitude	0 to 45 deg C 30 to 95% relative humidity less than 3000m altitude
Local User Interface	Monochrome graphic LCD, 3 push buttons	Monochrome graphic LCD, 3 push buttons	Monochrome graphic LCD, 3 push buttons
Physical dimensions	Recorder:113x65x30 mm PIB: 53 x 133 x 25 mm	Recorder: 240x120x58mm PIB: 127x66x27mm	Recorder:116x65x30 mm PIB: 78 x 45 x 22 mm
Weight	270 grams (including batteries)	1570 grams (including battery)	250 grams (including batteries)
Number of Patients Can Record Simultaneously	1 per Unit 2 Units per PC	1 per Unit 2 Units per PC	1 per Unit
Portable Design	Yes	Yes	Yes
Patient worn device	Yes	Yes	Yes
Main Recording unit	Yes	Yes	Yes
Patient Interface Box	Yes	Yes	Yes
Use for in-lab monitored studies	Yes	Yes	No
Use for ambulatory studies at home	Yes	Yes	Yes
General Functionalities:			
Data Collection	Yes	Yes	
Displays Raw Data during Recording	Yes, PC during in-lab use, or LCD on unit	Yes, PC during in-lab use, or LCD on unit	Yes, on LCD on unit
Built in Display for waveform preview	Yes – Integrated LCD including full disclosure waveform preview	Yes – Integrated LCD including full disclosure waveform preview	Yes - LCD

Characteristic	*Compumedics Somté PSG Recording System*	*Compumedics P-Series Sleep Monitoring System (predicate device)*	*Compumedics Somté Recording System (predicate device)*
Data display on PC for interpretation	Yes, during or after recording	Yes, during or after recording	Yes, after recording only
Data Analysis	Optional	Optional	Optional
Report Generation	Optional	Optional	Optional
Capable of Data Transfer for Analysis and Report Generation	Yes	Yes	Yes
Data Inputs	Generic and custom sensors. Data inputs as listed below	Generic and custom sensors. Data inputs as listed below	Generic and custom sensors. Data inputs as listed below
Signal Conditioning	Yes	Yes	Yes
Data Analysis (Computer, Computer-Assisted or manual).	Optional	Optional	Optional
Comprehensive Report Generation	Optional	Optional	Optional
Remote Sleep Surveillance	Yes, via broadband	Yes, via dial-up	No
Remote Capability to Monitor Lead Quality	Yes	Yes	No
Remote Capability to Monitor Recording Parameters	Yes	Yes	No
Look Forward/Watch Back Display	Yes	Yes	No
Data Recorded:			
# Channels of Data Recorded	Up to 19	Up to 18	Up to 13
Respiratory Effort Channels	2 Inductive plethysmography	2 Inductive plethysmography	2 Inductive plethysmography
Airflow	1 Nasal Cannula	1 Nasal Cannula	1 Nasal Cannula
Pressure	1 Nasal Cannula	1 Nasal Cannula	1 Nasal Cannula
Snore	From Cannula	From Microphone	From Cannula
Body Position	1 built in	1	1
SaO2	Yes	Yes	Yes
Heart Rate	Yes	Yes	Yes
Pulse Wave	Yes	No	Yes
Oximeter status (signal quality)	Yes	Yes	Yes
ECG Channels	Up to 2	1	Up to 2
EEG Channels	2 or 3	Up to 2	Up to 2
Chin EMG	Up to 2	1	Up to 2
Diaphragmatic EMG	Up to 1	optional	Up to 2
EOG	2	2	Up to 2
Leg Movement	Yes 2 Piezo Electric	Yes 2 Piezo Electric	Yes 2 Piezo Electric

Characteristic	*Compumedics Somté PSG Recording System*	*Compumedics P-Series Sleep Monitoring System (predicate device)*	*Compumedics Somté Recording System (predicate device)*
Aux AC	1 (or DC)	1	No
Aux DC	1 (or AC)	option	No
Impedance Check	Yes	Yes	No
Power Source	2 AA Batteries – Alkaline or NiMh	7.2V NiMh	2 AA Batteries – Alkaline or NiMh
Maximum recording duration	30 hours	15 hours	30 hours
Storage Media	CF Card up to 2Gb	CF Card up to 128Mb	CF Card up to 2Gb
Channel Sampling Rates	1-1024 Hz channel dependent	1-256 Hz channel dependent	1-1024 Hz channel dependent
Channel Storage Rates	1-256 Hz channel dependent	1-256 Hz channel dependent	1-256 Hz channel dependent
A/D Vertical Resolution (in Bits)	16	8 or 12	16
Average study size per 8 hour study	100Mb	30Mb	42Mb
Ability to calibrate DC channels	Yes	Yes	Yes
Communications to PC	IrDA & Bluetooth	Comms port	Not applicable
When used for ECG:			
Number of ECG channels	1 or 2	Not applicable	1 or 2
Sensors	Standard ECG electrodes	Not applicable	Standard ECG electrodes
Sample rate	1024	Not applicable	1024
Recording rate	256	Not applicable	256
Frequency response	0.048Hz to 102Hz (-3dB)	Not applicable	0.05Hz to 100Hz (-3dB)
Full scale range	10mV p-p	Not applicable	10mV p-p
ECG analysis software	Somté ECG Analysis V1.02	Not applicable	Somté ECG Analysis V1.02

6. Discussion of performance testing.

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

- Safety Tests to conform to IEC 60601-1, to ensure that there is no potential for detrimental effects on patients, other persons, animals or the surroundings. (refer to IEC60601-1 rpt-46275.1-6Dec06-SomtePSG-IEC60601-1 rpt). – refer to Attachment F.
- Electromagnetic Compatability Tests to IEC 60601-1-2 to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment. (refer to IEC60601-1-2 rpt-M060825-21Sep06-SomtePSG-IEC60601-1-2 rpt). – refer to Attachment F.
- Performance Validation was conducted, results were recorded and an internal and external Sleep authority generated a Somté PSG Performance Validation Report (refer to AC550-01 Woody Clinical Validation Report, AD052-01 Vampire Heart Rate Verification Report and AC551-01 Report to EN60601-1-4 for Woody-Somte PSG).). – refer to Attachment D.
- Compliance tested to hardware, software and firmware test specifications to ensure conformance to all design requirements.). – refer to Attachments C & D.

7. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Compumedics Limited that the SOMTÉ PSG SYSTEM 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

Mr. Gordon Ferguson
Compumedics Pty Limited
30-40 Flockhart Street
Abbotsford, Victoria 3067
AUSTRALIA

APR 14 2008

Re: K072201
Trade/Device Name: Somté PSG System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: April 10, 2008
Received: April 11, 2008

Dear Mr. Ferguson:

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) 276-0115. 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/industry/support/index.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

3 STATEMENT OF INDICATIONS FOR USE

510(k) Number: K072201

Device Name: SOMTÉ PSG SYSTEM

Indications for Use:

The ***Somté PSG*** is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various sleep disorders or sleep related respiratory or cardiac disorders.
The ***Somté PSG*** is designed for ambulatory and mobile operation and can be used in either the patient's home, the hospital or other environments, thus enabling patients to be investigated under as realistic conditions as possible.
The ***Somté PSG*** is only to be used under the direction of a physician.

Prescription Use ✓ AND/OR Over the Counter Use_____
(Per 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: K072201