K021176

JAN 21 2003

510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Limited summary for the Compumedics Somté Patient Recording Unit.

SUBMITTER'S NAME:	Compumedics Limited
ADDRESS:	1 Marine Parade Abbotsford, Victoria 3067 Australia
CONTACT PERSON:	Constance Bundy, C.G. Bundy Associates, Inc.
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	April 10, 2002

1. **Identification of device**
   Proprietary Name: Compumedics Somté System
   Common Name: Programmable Diagnostic Computer/EEG System
   Classification Status: Class II per 21 CFR Part 868.2375, Ventilatory Effort Recorder, Product Code: MNR
2. **Equivalent devices**
   Compumedics Limited believes the Compumedics Somté Patient Recording System is substantially equivalent to:

   The Compumedics Limited E-Series System (K000068) (for the sleep/cardio-respiratory recording component); and the Oxford Instruments Medilog® Excel 3 Holter Management System, (K002544) (for the electrocardiograph (ECG) recording component).

3. **Description of the Device**
   The Compumedics Somté Patient Recording System is a multi-functional, ambulatory recording device. The Somté is used to collect and store a patient's ECG and respiratory signals, which are then used as an aid in the diagnosis of cardiac and/or respiratory related sleep disorders by qualified physicians.

   The system is comprised of hardware and software, which provides up to 13 separate parameters for recording, review and analysis.

   The data are acquired from a combination of electrodes, sensors and transducers. Signal types can include electrocardiogram (ECG), pressure, airflow, snore, respiratory effort, body position, limb movement, oxygen saturation, pulse rate and pulse waveform.

   The electrodes and sensors used to acquire patient data are connected between the patient and the Somté System Recorder. Patient Studies are recorded using the

Compumedics Somté Software which allows the user to view, print, summarise, analyse and create Patient Study reports.

The Somté Patient Recording Unit has a built in Compact Flash Disk interface for storage and convenient transfer to review workstations. There is no proprietary hardware required to transfer the study data.

4. Intended use

The Somté System is a multi-functional ambulatory recording device intended to be used to collect and store signals related to sleep disorders, including respiratory signals, ECG signals and limb movement signals, to aid in the diagnosis of respiratory and/or cardiac related sleep disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2003

Compumedics, Limited
C/O Ms. Constance G. Bundy
C. G. Bundy Associates, Incorporated
6470 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K021176
Trade/Device Name: Compumedics Somté System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 18, 2002
Received: October 23, 2002

Dear Ms. Bundy:

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.

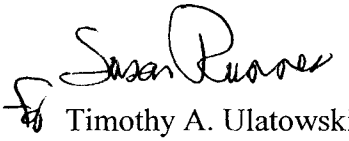
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K021176

Device Name: Compumedics Somté System

Indications for Use:

The Somté System is a multi-functional ambulatory recording device intended to be used to collect and store signals related to sleep disorders, including respiratory signals, ECG signals and limb movement signals, to aid in the diagnosis of respiratory and/or cardiac related sleep disorders.

The Somté System is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Somté System is only to be used under the direction and supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

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

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