K980879

JUL 16 1998

510(K) SUMMARY

Date prepared:	April 21, 1998
Contact:	CAS Medical Systems, Inc. 21 Business Park DR. Branford CT. 06405 (203) 488-6056 Fax (203) 488-9438
Contact person:	Ron Jeffrey Quality & Regulatory Affairs Manager
Trade name:	Oscillomate® 9002D EMS NIBP/Sp02 Monitor
Common names:	Physiological or Vital Signs Patient Monitor. Includes the following parameters: • Non-invasive Blood Pressure with Pulse rate • Pulse Oximeter & Heart Rate

Classification

Classification Name	21 CFR Section	Product Code	Class
Monitor, Physiological, Patient			2
Non-invasive Blood Pressure Measurement System	870.1130	74DXN	2
Oximeter	870.2700	74DQA	2

Predicate Devices

CAS is claiming substantial equivalence to the following legally marketed device:

Aspect	Device	510(k) number
Monitor	Propaq 100 SERIES Multi-parameter Patient Monitor	K910772
NIBP	Oscillomate 9001D NIBP by CAS Medical Systems	K972020 *
Oximetry	Model 8500 by Nonin Medical, Inc.	K893221

* As of the date of this submission this device was pending 510k approval.

Device Description

The 9002D Oscillomate NIBP / SP02 Monitor is a prescription device intended for use only by health care professionals.

The monitor is designed to monitor and spot check adult and pediatric patients for blood pressure, oxygen saturation, and pulse non-invasively in patient transport environments.

The monitor is portable, lightweight, and durable. The device and all of its accessories are further enclosed in a rugged Cordura nylon carry bag. Power is supplied by an internal rechargeable battery. An external battery charger is provided. Information is displayed in an easy to read LED display. NIBP Readings may be taken manually, or at preset intervals from 1 to 60 minutes. A message center display provides information and troubleshooting prompts. A history mode displays trends, previous readings and time readings were taken. Foreign language options and a data output port are included. The Sp02 function is derived from a pulse oximeter module mfg. by Nonin Medical, Inc.

Intended Use

The Oscillomate 9002 NIBP / SP02 monitor non-invasively measures blood pressure, oxygen saturation, and the pulse of the adult and pediatric patient in

EMS environments by health care professionals. It is not designed for continuous unsupervised monitoring.

Comparison of Technological Characteristics

The CAS Oscillomate 9002D NIBP / SP02 monitor and its monitoring parameters have essentially the same technological characteristics as the Oscillomate 9001 predicate devices with regard to design, materials and energy source. There are no new technological characteristics. With regard to the Propaq 100 SERIES monitors there are minor differences. The differences are shown below.

- Some of the Propaq 100 series use Electroluminescent (EL) displays as an option. The 9002D uses an LED display only
- The Propaq 100 series have an in-service mode that simulates patient data for training. The 9002D does not have this mode.
- The 9002D monitor is designed to operate in a protective carry bag. Propaq 100 series do not have a carry bag.
- The Propaq 100 series have alarms for set limits. The 9002D monitor does not have patient alarms.
- The 9002D monitor has 4 patient controlled foreign language choices. This is not available on the Propaq 100 series monitors.
- The Propaq 100 series with Sp02 have a tone pitch indicator which varies to reflect changes in oxygen saturation. This feature is not present in the 9002D monitor.

All devices are microprocessor driven electronic devices using the Oscillometric technique for NIBP and the absorption of red and infrared light passing through tissue for the oxyhemoglobin saturation (%Sp02) values.

Nonclinical Tests

Several bench tests were conducted to demonstrate safety and effectiveness of the Oscillomate 9002D and the monitoring parameters.

- Intra-device variability
- Combined device accuracy testing
- SP02 accuracy vs. simulation
- Environmental testing
- Electromagnetic Compatibility
- Safety - Medical and Dental Equipment
- Safety - Medical Electrical Equipment

Clinical Tests

- The Oscillomate 9002D meets the clinical performance criteria of AAMI/ANSI SP10: 1992.
- The Nonin® Pulse Oximeter component has passed Sp02 clinical accuracy testing.

Conclusions

In accordance with 21 CFR part 807.92(b)(3) and as presented in this premarket notification, CAS Medical Systems, Inc. concludes that the new device, the Oscillomate 9002D NIBP / SP02 Monitor is safe and effective and substantially equivalent to the predicate devices as described.

Other Information

CAS Medical Systems, Inc. will update this summary with additional information if requested by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1998

Mr. Ron Jeffrey
CAS Medical Systems, Inc.
Technology Applied to Medicine
21 Business Park Drive
Branford, CT 06405

Re: K980879
OSCILLOMATE 9002 NIBP / Sp02 Monitor
Regulatory Class: II (Two)
Product Code: DQA
Dated: June 23, 1998
Received: June 24, 1998

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980879

Device Name: **OSCILLOMATE 9002 NIBP / Sp02 MONITOR**

Indications For Use:

The Oscillomate 9002 NIBP / Sp02 Monitor Non-invasively measures blood pressure, oxygen saturation and the pulse of the adult and pediatric patient in EMS environments by health care professionals. It is not designed for continuous unsupervised monitoring.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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and Neu
510(k) Number K980879

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

(Optional Format 1-2-96)