K972020

MAY 5 1998

510(K) SUMMARY

Name of device:	Oscillomate 9001D Non-invasive Blood Pressure Monitor
Submitted by:	CAS Medical Systems, Inc.
Date prepared:	May 28, 1997
Contact person:	Ron Jeffrey Quality & Regulatory Affairs Manager

Device trade name:	Oscillomate® 9001D NIBP Monitor
Common name:	Blood Pressure Monitor
Classification name:	Non-invasive Blood Pressure Measurement System (870.1130)

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

Propaq model 106EL Portable Patient Monitor

DEVICE DESCRIPTION

General information:

The 9001D monitor is compact, lightweight, and durable. The device is housed in and ABS enclosure. 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. 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 previous readings and time readings were taken.

The Oscillometric technique monitors the changes of pressure caused by the flow of blood through the artery. The monitor will inflate the cuff around the patients arm to a value that occludes the artery. The monitor then deflates the cuff in steps. As the cuff pressure goes down, blood continues to flow through the artery. The increasing blood flow causes the amplitude of the pressure pulses in the cuff to increase. As the monitor steps down further, the pulses will reach a peak amplitude and then start to decrease with additional pressure steps. The rising and falling of the amplitude of these pressure pulses as the cuff pressure is stepped down, creates a curve that is used to find the systolic pressure and diastolic pressure. Counting the pulses over a time period will give a pulse rate. Motion artifact rejection techniques are used to provide accurate results under most operating conditions.

INTENDED USE

The 9001D is designed to measure the blood pressure of the adult or pediatric patients primarily in the emergency care environment. The monitor automatically inflates an occluding cuff and, using the Oscillometric measurement technique, determines systolic, diastolic, and pulse rate.

The Oscillomate 9001D is compact lightweight and portable, allowing it to be easily transported and used in a variety of clinical settings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The tables on the following pages compare characteristics between the CAS Oscillomate 9001D and the predicate device "Propaq 106EL". There are no major differences in blood pressure technological characteristics between the two devices.

NOTE: The Propaq 106EL is a multi-parameter monitor with other functions aside from non-invasive blood pressure. The comparison table does not address the other parameters.

NON-CLINICAL PERFORMANCE TESTING AND SUBSTANTIAL EQUIVALENCE

The Oscillomate 9001D and the predicate device Propaq 106EL were evaluated in a patient transport environment that represents their primary area of use. A comparative study was made to evaluate both monitors in an ambulance. The series of tests measured subjects while the ambulance was in motion.

This test includes the protocol, data and final report. See 510(k) appendix 1.

The report concludes that the 9001D provides equivalent performance when encountering patient motion, road noise and vibration conditions in a vehicular transport environment.

The Oscillomate 9001D and the predicate device Propaq 106EL were compared for accuracy using a patient simulation device over a range of input conditions.

The test data concludes that the Oscillomate 9001D met the conditions for acceptance and outperformed the predicate device. See 510(k) appendix 2.

CLINICAL PERFORMANCE TESTING AND SUBSTANTIAL EQUIVALENCE

CAS submitted its NB module to AAMI/ANSI SP10: 1992 clinical accuracy testing using a model 9010 monitor as a test platform. The 9010 monitor, originally intended to be a dual parameter monitor with a pulse oximeter, was never developed or marketed. The NB module is unchanged from the testing performed in the study to its new use in the 9001D monitor.

The clinical testing includes a clinical trial protocol, data and analysis of results. See 510(k) appendix 10.

The Oscillomate 9001D meets the clinical performance criteria of AAMI/ANSI SP10: 1992. The predicate device makes the claim that it meets AAMI/ANSI SP10: 1987 standard for clinical accuracy with the NIBP portion of their monitor.

CONCLUSIONS DRAWN FROM CLINICAL AND NON-CLINICAL TESTS

CAS has tested and met all aspects of the AAMI/ANSI SP10: 1992 (510k section 5) which includes overall system efficacy, through clinical trial, environmental performance and stability, safety requirements, and performance requirements. For non-invasive blood pressure monitoring this is the standard to meet.

Other non-clinical testing has been performed as well. Included here are UL544, IEC 601-1, IEC 601-1-2, IEC 601-2-30, BS EN 1060-1, ISTA packaging shipping testing, and IEC 68 (series) environmental shock and vibration testing.

CAS has passed all submitted testing.

List of Predicate Device

Monitoring Function	Predicate Device	Date of Substantial Equivalence and K Number
Non-Invasive Blood Pressure(NIBP) using oscillometric method	Protocol Systems, Inc. PROPAQ 100 Series Ultra-Portable Patient Monitor	K910772 NIBP Module referenced in K914838 January 10, 1992

Feature		CAS OSCILLOMATE 9001D	Protocol Propaq 100 series	Difference and Justification
1. Intended Use	Physical environment	Hospital ER, Clinics, Emergency Medical Service	Hospital, Air medical/emergency transport, field medical application	CAS device is not designed as a bed-side monitor.
	Patient Population	Adult and Pediatric	Adult and Pediatric	None
2. Monitoring Mode - using blood pressure cuff	Non-invasive Blood Pressure	Uses single-hose, inflatable cuff to determine systolic and diastolic.	Uses single-hose, inflatable cuff to determine systolic, diastolic and mean arterial pressure	None
	Pulse Rate	Determines pulse rate through cuff pressure pulsation	Determines pulse rate through cuff pressure pulsation	None
3. NIBP Functions	Blood Pressure determining method	Oscillometric, step-wise de-pressurization of cuff	Oscillometric	None
	Operating modes	MANUAL Automatic cycles of 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes	MANUAL Automatic cycles of 1, 2, 3, 5, 10, 15, 30 and 60 minutes TURBOCUFF for 5 minutes	Continuous (TURBOCUFF) measurements mode is only a convenience feature. It does not provide added benefit to the patient when health provider is operating the device next to the patient in close quarters such as field situation.
	Typical Determination Time	25 seconds	15 to 40 seconds	Similar
	Calibration	Digital manometer mode	On-screen manometer	None
	Alarms	Equipment/Measurement error indications only	Patient parameters and Equipment/Measurement errors	CAS device does not provide patient parameter alarms for the simple reason that patients are closely observed during transpo It is not being used as a bed-side monitoring device.
4. Blood pressure Range	Systolic	25-255 mmHg	30-250 mmHg	Both ranges cover majority of patient population adequately.

Feature		CAS OSCILLOMATE 9001D	Protocol Propaq 100 series	Difference and Justification
4. CONT.	MAP	18-255 mmHg	25-240 mmHg	Same as above
	Diastolic	10-220 mmHg	20-230 mmHg	Same as above
5. NIBP System Efficacy (Voluntary Performance Standards)	Blood Pressure Accuracy	Meets ANSI/AAMI SP-10, 1992. Mean difference in Systolic(and Diastolic) pressure comparison: ± 5mmHg or less with a standard deviation of 8 mmHg or less.	Meets ANSI/AAMI SP-10, 1987. Mean Systolic(and Diastolic) pressure comparison: ± 5mmHg or less with a standard deviation of 8 mmHg or less.	None
6. Pulse Rate Range	Design specification	40-240 beats per minute	25-200 bpm	Both ranges cover majority of patient population adequately.
7. Pulse Rate Accuracy	Design specification	±2 bpm or ±2%, whichever is greater	within ± of 6 bpm or 6%, whichever is greater	No significant difference
8. Measurements Storage	Design specification	Stores measurements within the last 5 hours of up to 99 cycles	Up to 128 readings that are less than 8 hours old	No significant difference
9. AC Power Adapter	Input Requirement	Optional 120 VAC or 100-240 VAC	Optional 100 VAC, 120 VAC or 220-240 VAC	No significant difference
10. Battery Power	Battery Type	Rechargeable sealed lead acid, 6V 3.2AH	Rechargeable sealed lead acid, 8V 3AH.	No significant difference
	Low, or Dead Battery Alert	Displays warning on battery condition; does not make measurement in dead battery condition	Displays LOW BATT alarm	No significant difference
	Charge Time for a depleted pack	12 hours	~8 hours	Both provide overnight charging method.
	Operating Time on a fully charged pack	300 reading at 1-minute automatic cycles; 7 hour continuous	6.5 hours, NIBP every 15 minutes	CAS device is dedicated to BP measurement only. It has more reserved power to run electromechanical components
11. Alarm Indicators	Visual	Blinking 8-character message display	RED LED and on-screen message	No significant difference
	Aural	Short Audio beeps for alert	Beeper	No significant difference
12. Physical Characteristics	Measurement Data Display	RED 8-segment LED's	Backlit LCD or EL 276x128 pixel graphical display	User preference item. No graphical display for NIBP
	Message Display	RED 8-character dot-matrix LED message center	same as above	Same as above
	Unit Size (H x W x D)	7.5" x 8" x 5"	6.6" x 8.3" x 4.8"	No significant difference

Feature		CAS OSCILLOMATE 9001D	Protocol Propaq 100 series	Difference and Justification
12. CONT.	Unit Weight	4.5 lb.	5.8 lb..	No significant difference
	Unit mounting/carrying	A padded, fabric carrying bag is an integral part of the monitor, battery and cuff storage system.	Unit with carrying handle, optional carrying bag for transport.	CAS device is a more convenie and complete package for the intended environment.
13. Environmental	Operating Altitude	Tested to -500 to +10,000 ft. Measurement accuracy is referenced to local atmospheric pressure and will not be affected by operating altitude	-1,000 to +15,000 ft.	No significant difference
	Operating Temperature	0° to 50° C	0° to 50° C	None
	Operating Humidity	15 to 90%(non-condensing)	0 to 97%(non-condensing)	No significant difference
	Storage Temperature	-20° to 70° C	-20° to 60° C	No significant difference
	Storage Humidity	15 to 95%	0 to 97%	No significant difference
	Electromagnetic Compatibility	EN 60601-1-2 IEC 801-1-2; IEC 801-1-3 IEC 801-1-4; IEC 801-1-5 CISPR - 11	IEC-801-2, level 4 ESD VDE 0871 class B EMI FDA MDS-201-0004(emissions only)	CAS elected to use the current International Standards.
	Shock & Vibration Resistance	IEC 68-2-27; SHOCK IEC 68-2-6; Sin. VIBRATION IEC 68-2 -34; RANDOM VIBRATION, wide band	MIL-T-28800	CAS elected to use FDA's Performance Standard for Infa Apnea Monitor as guidance for S&V resistant testing
14. Safety Characteristics	Electrical	UL544, EN 60601-1	UL, CSA, TUV and others	None
	Cuff Over-Pressurization limits	Software Limit: 290 mmHg Redundant switch: 330mmHg (Meets IEC 601-2-30, AAMI SP-10)	Software Limit: 260 mmHg Redundant switch: 330mmHg (Meets IEC 601-2-30, AAMI SP-10)	No significant difference
	Prolonged Cuff Inflation time-out	Up to 120 seconds (Meets IEC 601-2-30, AAMI SP-10)	Up to 180 seconds (Meets IEC 601-2-30, AAMI SP-10)	CAS uses a shorter time for patient comfort.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1998

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

Re: K972020
OSCILLOMATE 9001D NON-Invasive Blood Pressure Monitor
Regulatory Class: II (Two)
Product Code: DXW
Dated: April 17, 1998
Received: April 28, 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): K 972020

Device Name: **OSCILLOMATE 9001D NON-INVASIVE BLOOD PRESSURE MONITOR**

Indications For Use:

The Oscillomate 9001D monitor non-invasively measures the blood pressure of adult and pediatric patients primarily in the emergency care environment. The monitor automatically inflates an occluding cuff and, using the Oscillometric measurement technique, determines systolic, diastolic and pulse rate.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K 972020

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

(Optional Format 1-2-96)