K982776

CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
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NOV 2 1998

510(K) SUMMARY

Date prepared: August 5, 1998

Contact:
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(203) 488-6056
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Contact person:
Ron Jeffrey
Quality Assurance Manager

Device trade name: 9303 Neonatal / Adult Vital Signs Monitor

Common names: Physiological or Vital Signs Patient Monitor.

Includes the following parameters:

- Non-invasive Blood Pressure with Pulse rate
- Pulse Oximeter & Pulse Rate
- Predictive Thermometer

Classification

Classification Name	21 CFR Section	Product Code	Class
Monitor, Physiological, Patient		74MHX	2
Non-invasive Blood Pressure Measurement System	870.1130	74DXN	2
Oximeter	870.2700	74DQA	2
Clinical Electric Thermometer	880.2910	80FLL	2

Predicate Devices

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

Aspect	Device	510(k) number
Non-invasive Blood Pressure	Oscillomate 9300 NIBP by CAS Medical Systems	K925402
Non-invasive Blood Pressure	Oscillomate 9002D NIBP by CAS Medical Systems	K980879
Oximetry	Model 8500 by Nonin Medical, Inc.	K893221
Temperature	SureTemp 679 by Welch Allyn	K964643 K943695

Device Description

The 9303 Neonatal / Adult Vital Signs Monitor is a prescription device intended for use only by health care professionals.

The monitor is designed to monitor and spot check adult, pediatric and neonatal patients for blood pressure, oxygen saturation, pulse and temperature non-invasively in a variety of clinical settings.

The monitor is portable, lightweight, and durable. The user selects either the adult or neonatal application for NIBP. Power is supplied by an internal lead acid rechargeable battery. The battery is charged by plugging monitor to an AC power source. Information is displayed in an easy to read LED display. NIBP Readings may be taken manually, or at automatic, operator selected intervals. A STAT mode is available for a rapid series of NIBP measurements. A message center display provides system alarm messages, operating modes, battery state and troubleshooting prompts. A history mode displays previous NIBP and Sp02 readings which can be sent to an optional printer. The monitor can operate in one

of four languages which the operator may change. There are NIBP and Sp02 patient alarms to warn the user of any measurement parameter outside the range of a user set or factory default value. A test mode may be activated to test for pneumatic leaks and calibration. The predictive temperature function may be either oral, axillary or rectal with appropriate probe.

The 9303 monitor is year 2000 compatible. The monitor includes a time stamp function for the printout of NIBP values and a history function in non-volatile memory. The history function is a short term (hours) storage and is not effected by yearly changes. The monitor will show the year 2000 as "00". Accounting for leap year is not a problem.

Intended Use

The 9303 Neonatal / Adult Monitor is intended for use for non-invasive monitoring of blood pressure, oxygen saturation, pulse and the temperature of the adult, pediatric and neonatal patient in the care of health care professionals.

Comparison of Technological Characteristics

The CAS 9303 Monitor and its monitoring parameters have essentially the same technological characteristics as the predicate devices with regard to design, materials and energy source. There are no new technological characteristics. The 9303 monitoring parameters and the predicate devices monitoring parameters utilize the following technologies:

- Non-invasive Blood Pressure and Pulse: **Oscillometrics**
- Pulse Oximetry and Heart Rate: **Nonin Medical Inc.® Red and Infrared Oximetry.**
- Predictive Thermometer: **SureTemp® Microprocessor based Thermister Predictive Thermometer.**

Nonclinical Tests

Several other tests were conducted to demonstrate safety and effectiveness of the 9303 and the monitoring parameters.

- Intra-device variability
- Environmental testing (Temperature and Humidity)
- Electromagnetic Compatibility
- EN 60601-1 Safety - Medical Equipment
- Mechanical Shock and Vibration
- Battery and AC Testing

Clinical Tests

- The 9303 w/ NB NIBP Technology meets the clinical performance criteria of AAMI/ANSI SP10: 1992.
- The Nonin® Pulse Oximeter component has passed Sp02 clinical accuracy testing.
- The SureTemp® Thermometer component has passed clinical testing orally and rectal for adults and children under three.

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, 9303 Adult / Neonate Vital Signs 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

NOV 2 1998

Mr. Ron Jeffery
QA/RA Manager
CAS Medical Systems, Inc.
21 Business Park Drive
Branford, CT 06405

Re: K982776
Model 9303 Neonatal/Adult Vital Signs Monitor
Regulatory Class: II (two)
Product Code: DQA
Dated: August 5, 1998
Received: August 6, 1998

Dear Mr. Jeffery:

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 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). 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, ²Misbranding by reference to premarket notification² (21CFR 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/dsma/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: K982776

Device Name: CAS Medical Systems, Inc. 9303 Neonatal/ Adult Vital Signs Monitor

Indications For Use:
The 9303 Neonatal/ Adult Vital Signs monitor is indicated for non-invasive monitoring of blood pressure, oxygen saturation, pulse and temperature of adult, pediatric and neonatal patients in the care of health care professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982776