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CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Ref.: K033048

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Trade Name: CAS 740 Series Monitor

Common Name: Vital Signs Monitor

Classification Name: Noninvasive Blood Pressure Measurement System

EQUIVALENCE

The CAS 740 Monitor is equivalent to the following devices:

- CAS 9303 Neonatal / Adult Vital Signs Monitor (K982776);
- CAS 9001 EMS NIBP Monitor (K982135);
- CAS 9002 EMS NIBP / Sp02 Monitor (K980879);
- Nellcor Puritan Bennett N-550 Pulse Oximeter (K021090);
- Nellcor Puritan Bennett N-595 Pulse Oximeter (K012891);
- Masimo Set 2000 Pulse Oximeter / accessories (K990966)

DESCRIPTION

The CAS 740 Monitor is a replacement monitor based on the existing 9303 Vital Signs Monitor, and the CAS 9001 or 9002 EMS monitors. The 740 are primarily a repackaging of these monitors. The primary parameter is non-invasive blood pressure, which is included in all models (see below). Blood pressure measurement is based on oscillometric technology. The additional two parameters are pulse oximetry and temperature.

A purchaser has pulse oximetry choices that include modules manufactured by Masimo, Nellcor or Nonin.

The temperature parameter utilizes predictive technology from SureTemp™ (Welch Allyn Inc.)

The monitor is a rugged, portable and lightweight unit widely adaptable for many applications and mounting schemes. Used for spot-checking or continuous monitoring, features include an easily replaceable Nickel Metal Hydride rechargeable battery pack, wireless infrared printer communication,
and many more. The table below defines the different models within the 740 series and the relationship to the CAS predicate devices

The monitor, its equivalent and parameters:

Model(s)	CAS Equiv.	Parameters (Variations)
740-3MS, 740M-3MS	9303, 9001	ND NIBP, Masimo Sp02 & W/A Temp - domestic and international versions 100 – 240 VAC, and RS 232; (12VDC version; mounting versions available)
740-3NL, 740M-3NL	9303, 9001	ND NIBP, Nellcor Sp02 & W/A Temp - domestic and international versions 100 – 240 VAC, and RS 232; (12VDC version; mounting versions available)
740-3NN, 740M-3NN	9303, 9001, 9002	ND NIBP, Nonin Sp02 & W/A Temp - domestic and international versions 100 – 240 VAC, and RS232; (12VDC version; mounting versions available)

740 Series Intended Use

The CAS 740 Series Vital Signs Monitor is indicated for use for non-invasive monitoring of blood pressure, oxygen saturation, pulse and temperature of adult, pediatric and neonatal patients, in the care of health professionals.

SUBSTANTIAL EQUIVALANCE COMPARISON – PREDICATE(S) VS. 740

CATEGORY	CAS 9303, 9001 AND 9002 (predicate)	CAS 740 SERIES
Indications for use	The CAS predicate devices are indicated for use for non-invasive monitoring of blood pressure, oxygen saturation, pulse and temperature of adult, pediatric and neonatal patients in the care of health professionals. The 9001 and 9002 monitors are further indicated for use with the EMS / transport user, relying on a rechargeable battery and charger. These models have no direct mains AC input.	The CAS 740 Series devices are indicated for use for non-invasive monitoring of blood pressure, oxygen saturation, pulse and temperature of adult, pediatric and neonatal patients in the care of health professionals. In summary, the 740 series monitor has all of the same indications for use as its predicate device. This includes: condition or disease monitored, prescription vs. over the counter, part of the body applied to, frequency of use, physiological purpose and patient population.
Target population	9303 family - adults, pediatric and neonatal patients. 9001 and 9002 – adults and pediatric patients only.	740 series – adults, pediatric, infant and neonatal patients.
Design	9303 family is comprised of three models: 9301 – non-invasive blood pressure only; 9302 – non-invasive blood pressure and pulse oximeter only; 9303 - non-invasive blood pressure, pulse oximeter and temperature. The 9001 is similar to the 9301 and the 9002 is similar to the 9302. All predicate CAS monitors are small lightweight and portable. The entire line of predicate monitors utilizes modular components for non-invasive blood pressure, pulse oximetry and temperature, if included. In all cases the non-invasive blood pressure module is a CAS design and the same item; (NB non-invasive blood pressure module).	The 740 series is designed to be a multi-parameter monitor. The 740 series will replace the 9301, 9302, 9303, 9001 and 9002 monitors. The 740 series is small lightweight and portable. Like its predicate, the 740 utilize modular parameters for non-invasive blood pressure, pulse oximetry and temperature. CAS designs the blood pressure component, called the ND Plus. The primary difference with the ND Plus, as compared to the predicates NB board, is its smaller size and its lower power use. Also, there is the additional of a secondary safety processor. The boards are similar in that ND Plus has the same front-end control and the same basic algorithm as the NB board.

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	Where a pulse oximeter is included it is a purchased OEM module from Nonin Medical Systems. The temperature function is only available in the 9303 monitors and is an OEM purchased predictive temperature module manufactured by Welch Allyn.	Where a pulse oximeter is included, CAS provides three possible OEM options. The predicate device provided only one. The customer has the option of selecting the pulse oximeter of their choice. Available are the Masimo, Nellcor and Nonin (same as predicate) pulse oximeters. The FDA in the manufacturers own finished medical devices has cleared all three of these pulse oximeters. The temperature function is available if desired. Like the predicate, it is an OEM purchased predictive temperature module manufactured by Welch Allyn. The FDA has cleared this module, in the manufacturers monitor, for marketing. In summary, with the exceptions noted above, and the new look of its case design, the 740 is essentially the same as the predicate devices.
Materials	Monitor case – ABS U.L. approved material; Monitor interior – Series of PC boards (Control / Display, interface and non-invasive blood pressure) If ordered with pulse oximeter or temperature, these would be additional PC board modules. Power center – 9303 family has AC mains input and a rechargeable lead acid type battery. 9001/9002 monitors have no AC mains and get power from a rechargeable power supply (or direct DC from transport vehicle) and lead acid battery. Non-invasive blood pressure	Monitor case – ABS U.L. approved injection molded material. This monitor is a custom industrial design Monitor interior – Series of PC boards (Control / Display, interface and non-invasive blood pressure) If ordered with pulse oximeter or temperature, these would be additional PC board modules. Power center – 740 series has AC mains and a rechargeable Nickel Metal Hydride customer replaceable battery. A DC version is part of the series where the power is obtained from the transport vehicle. Non-invasive blood pressure module (NIBP) – Of the three possible

CATEGORY	CAS 9303, 9001 AND 9002 (predicate)	CAS 740 SERIES
	module (NIBP) – Of the three possible parameters offered, this module is the only one designed and manufactured by CAS. All monitors in this group contain the NB NIBP module version which consists of microprocessor, circuitry, software, valves, pump transducer, and hardware.	parameters offered, this module is the only one designed and manufactured by CAS. All monitors in this group contain the ND Plus NIBP module version, which consists of microprocessor, circuitry, software, valves, pump transducer, and hardware. The "design" section contains reference to the subtle differences.
	Pulse oximeter module – This parameter is an option in the 9302 and 9002 only. It is the same module in both cases and is manufactured by Nonin Medical Systems.	Pulse oximeter module – As with the predicate monitors, the same Nonin module is one of the three types offered. The other two types of pulse oximeters are Masimo and Nellcor (Tyco Healthcare). These are actively marketed OEM devices designed for use by other manufacturers as well as the company's own branded devices. All three types of pulse oximeter occupy the same footprint and consume the same power.
	Temperature module (9303 only) – See design section.	Temperature module – The 740 has this parameter. See "Design" section.
	Components / Accessories – Included are blood pressure cuffs, inflation tube, power cord, users manual, at a minimum. For monitors with the options of pulse oximeter and temperature, the manufacturers recommended accessories are included.	Components / Accessories – Included are blood pressure cuffs, inflation tube, power cord, users manual, at a minimum. These are the same as the predicate devices. For pulse oximetry and temperature, the manufacturers recommended accessories are included.

CATEGORY	CAS 9303, 9001 AND 9002 (predicate)	CAS 740 SERIES
Performance (Clinical and non-clinical)	With regard to non-invasive blood pressure, CAS has tested and passed performance qualification to the SP10 requirements. There is historical acceptance of these monitors from an accuracy viewpoint. CAS has very few complaints related to accuracy issues.	With regard to non-invasive blood pressure, CAS has tested and demonstrated ND Plus performance equivalent to the NB module in bench test simulations. No new issues of safety and effectiveness were raised. Note: Predicate devices use NB NIBP module. 740 Series uses the ND Plus NIBP module. In addition, the 740 monitor has undergone a series of clinical studies in accordance with AAMI SP10:2002, with results meeting the requirements of the standard In summary, performance equivalence has been demonstrated.
Sterility	None of the equipment or its accessories is sterilized.	None of the equipment or its accessories is sterilized.
Biocompatibility	All patient contact equipment and accessories have been tested, at some level, for biocompatibility.	All patient contact equipment and accessories have been tested for biocompatibility. Where the accessories are provided "ready for sale" by the manufacturer of the pulse oximeter and temperature components, there is documentation showing that the manufacturer has obtained adequate biocompatibility results.
Mechanical Safety	These predicate devices have undergone mechanical safety testing as part of the successful, and ongoing evaluation by Underwriters Laboratories as well as testing to the medical equipment safety standard, IEC60601-1 and its applicable collateral and particular standards.	The 740 series monitors have been evaluated to the following standards: UL2601-1, IEC 60601-1, IEC 60601-2-30, IEC 60601-2-49, AAMI SP10 and other collateral and particular safety standards. A follow-up services program is planned for quarterly inspection for these standards. In summary, the 740 has received greater testing for mechanical safety than the predicate devices.
Chemical Safety	Not applicable to these products	Not applicable to these products

CATEGORY	CAS 9303, 9001 AND 9002 (predicate)	CAS 740 SERIES
Anatomical Sites	Blood pressure - arms and thigh (Neonates – arm and leg) Sp02 – fingers and toes Temperature – Orally or rectally (neonates – axillary)	Blood pressure - arms and thigh (Neonates – arm and leg) Sp02 – fingers and toes Temperature – Orally or rectally (neonates – axillary) In summary, there is no difference in anatomical sites.
Human Factors	With these monitors human factors issues were not monumental from the beginning. Human factors were considered during the development of the monitors. Some of the issues that did persist were designed out during the product lifetime	With the 740 series monitor additional human factors were employed. Examples of these are: ✓ Easier battery access for replacement; ✓ Visible battery state of condition; ✓ Auto off to save battery life; ✓ Attached label explaining symbols used; ✓ All cables and cords better located to avoid tangling; ✓ Designed for ease of assembly; ✓ Numerous mounting opportunities – tables, pole, wall or rail; ✓ Wireless communication to printer; ✓ More rugged than predicates; ✓ Additional languages offered.

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Energy used	The 9303 monitor contains a switching power supply which handles input of 100 to 250VAC 50/60 Hz at 0.3A. This power runs the monitor and charges a 6VDC lead acid battery. The 9001 & 9002 monitors do not have internal power supplies. These monitors, designed with portability EMS conditions in mind, contain a 6VDC Lead Acid battery, which is charged by a 120VAC power supply.	The 740 series contains the same power supply, essentially the same as the 9303 with the exception of the battery, which in this case is a 7.2 volt Nickel Metal Hydride (NiMH) battery pack. A version of the monitor is available for transport use where its power is derived from a vehicles 12VDC power. In this case there is no internal power supply or a mains connection. This version also uses the same battery pack. In summary, the move to NiMH greatly improves capacity and charge time.
Compatibility with environment and other devices	In general these devices do not represent environmental compatibility challenges. Compatibility with other devices is clearly specified by the manufacturer in the user manuals. Product safety and EMC rules require that limits be established by testing and documented.	In general these devices do not represent environmental compatibility challenges. Compatibility with other devices is clearly specified by the manufacturer in the user manuals. Product safety and EMC rules require that limits be established by testing and documented. In general there is equivalence here, however the safety and EMC testing authority has required that tighter controls be placed on connection to other devices.
Where used	Hospitals, intra-hospital and inter-hospital transport, clinics, doctor's office, dental offices, emergency vehicles, and first responders. Not indicated for home use	Hospitals, intra-hospital and inter-hospital transport, clinics, doctor's office, dental offices, emergency vehicles, and first responders. Not indicated for home use In summary, there is no difference here.

CATEGORY	CAS 9303, 9001 AND 9002 (predicate)	CAS 740 SERIES
Standards met	UL2601 or 544, EN 60601-1, EN 60601-1-2, EN 60601-2-30, EN 1061 and SP10 (accuracy)	UL2601-1, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-30, IEC60601-2-49, EN 865, and AAMI SP10:2002. In summary, There were more standards met and in some cases they were updated revisions.
Electrical Safety	These predicate devices have undergone mechanical safety testing as part of the successful, and ongoing evaluation by Underwriters Laboratories as well as testing to the medical equipment safety standard, IEC60601-1 and its applicable collateral and particular standards.	The 740 monitor has undergone electrical safety testing as part of the successful, and ongoing evaluation by Underwriters Laboratories as well as testing to the medical equipment safety standard, IEC60601-1 and its applicable collateral and particular standards. In summary, the 740 has received greater testing for electrical safety than the predicate devices.
Thermal Safety	These devices do not present thermal safety risks. Some aspects of over-temperature are evaluated during safety testing.	These 740 series does not present thermal safety risks. Some aspects of over-temperature are evaluated during safety testing. In summary, there are no differences.
Radiation safety	Not a risk	Not a risk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

JUN - 1 2004

Mr. Ron Jeffrey
Director, Regulatory Affairs
CAS Medical Systems, Incorporated
44 East Industrial Road
Branford, Connecticut 06405

Re: K033048
Trade/Device Name: CAS 740 Series Monitor Models 740-3MS, 740M-3MS, 740-3NL, 740M-3NL, 740-3NN, 740M-3NN
Regulation Number: 870.1025
Regulation Name: Patient Physiologic Monitor
Regulatory Class: II
Product Code: MHX
Dated: May 13, 2004
Received: May 14, 2004

Dear Mr. Jeffrey:

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,

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

Indications for Use

510(k) Number: K033048

Device Name: 740 Series monitor

Indications for use: The CAS 740 Series Vital Signs Monitor is indicated for use for non-invasive monitoring of blood pressure, oxygen saturation, pulse and temperature of adult, pediatric and neonatal patients, in the care of health professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K033048

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

510(k) Number: K033048