JUN 23 2005

K050844

CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL ROAD, BRANFORD, CONNECTICUT 06405

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

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Prepared: April 1, 2005

Trade Name: CAS 750C Series Monitor

Common Name: Multi-Function Patient Monitor

Classification Name: Carbon Dioxide Gas Analyzer (73CCK)

EQUIVALENCE (Predicate Device)

The CAS 750C Series Monitor is equivalent to the following devices:

- Oridion Polaris 2004 (K040011);
- Masimo SET 2000 Pulse Oximeter (K990966);
- Nellcor N-595 Pulse Oximeter (K012891).
- CAS 740 Series Patient Monitor (K033048);

DESCRIPTION

The CAS 750C Series Monitor is a multi-parameter patient monitor based on the exterior design and platform of the CAS 740 Vital Signs Monitor. The 750C features a capnograph equivalent to the Oridion Polaris 2004 End-Tidal C02 for the continuous non-invasive measurement and monitoring of carbon dioxide concentration of expired and inspired breath. Monitors in the series also have a choice of MasimoSET® or Nellcor® OxiMAX® Sp02 technology, and CAS MAXNIBP®. All four monitors in the 750C series have end-tidal C02 and a pulse oximeter. Two of the four have an additional third parameter consisting of non-invasive blood pressure. Blood pressure measurement is based on the CAS oscillometric technology, and is identical to that which is found in the CAS 740 series vital signs monitors (K033048).

The 750C monitor is a rugged, portable and lightweight unit widely adaptable for many applications and mounting schemes. Used for spot-checking or continuous monitoring, its features include an easily replaceable Nickel Metal Hydride rechargeable battery pack, wireless infrared printer communication, and a backlit LCD display with both waveform and a numeric display.

The monitor and parameters:

Model(s)	Parameters (Variations)
750C-2MS (750CM-2MS)	Oridion $EtC0_2$ and Masimo $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included)
750C-2NL, (750CM-2NL)	Oridion $EtC0_2$ and Nellcor $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included)
750C-3MS, (750CM-3MS)	Oridion $EtC0_2$, Masimo $Sp0_2$, and CAS NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included)
750C-3NL, (750CM-3NL)	Oridion $EtC0_2$, Nellcor $Sp0_2$, and CAS NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included)

750C Series Intended Use

The 750C monitor is intended to continuously calculate and display the following physiological vital signs: end tidal carbon dioxide, respiration rate, capnograph waveform, functional arterial oxygen saturation, pulse rate, plethysmograph waveform, and an optional non-invasive blood pressure measurement of systolic, diastolic, mean arterial pressures along with pulse rate derived from a NIBP pressure waveform. The 750C is intended for monitoring of adult, pediatric and neonatal patients in the care of health care professionals.

Comparison of Technological Characteristics

The 750C monitor is derived from the CAS 740 (K033048) with regard to form factor and general overall look. A number of identical components are found in both products, most especially the non-invasive blood pressure MAXNIBP® parameter, choice of pulse oximeters; Masimo SET® or Nellcor® OxiMax®. In the 740 predicate, NIBP is the primary parameter, and the secondary are the same two possible pulse oximeters. The 750C series adds a new primary parameter of a Carbon Dioxide Gas Analyzer (Capnometer). The predicate for this portion of the device is the Oridion Polaris 2004 (K040011). CAS makes use of the OEM modules, and appropriate accessories in accordance with the manufacturer's recommendation with no modifications. Some key differences between 740 and 750 are the increased wattage of the switching medical grade power supply and the graphical display capable of numeric characters and waveforms.

Nonclinical Performance Testing to Show Substantial Equivalence

The model 750C will be tested in accordance with the following standards as per CAS Product Performance Specifications prior to release to market. The following non-clinical tests will be performed:

- UL60601-1 (w/ CSA 22.2 No. 60601-1) Safety testing for use of the UL Classified mark;
- IEC60601-1 Safety of Medical Electrical Equipment;
- EN60601-1-2:2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC60601-1-4 Medical Electrical Equipment – Collateral standard: Programmable Electrical Medical Systems;

- IEC60601-2-30 Safety of Medical Electrical Equipment – Particular Requirements for Automatic Cycling Indirect blood Pressure monitoring Equipment;
- IEC60601-2-49 Safety of Medical Electrical Equipment – Particular Requirements for the Safety of multifunctional Patient Monitoring Equipment;
- EN 865 Pulse Oximeters – Particular Requirements;
- EN 864 Capnometers for use with Humans – Particular Requirements;
- ANSI/AAMI SP10:2002 – Electric or Automated Sphygmomanometers (accuracy, performance and environmental);
- NIBP Monitor Guidance V1.0 March 1997;
- IEC68-2-6, -27 and –34 Mechanical Shock and Vibration;

Clinical Testing to Show Substantial Equivalence

The OEM parameter suppliers (EtC02 an Sp02) have demonstrated successful clinical performance within their own premarket submissions. Those modules are unchanged for inclusion within the model 750. Fully configured model 750 devices were sent to each OEM module manufacturer for performance testing.

The NIBP parameter has been demonstrated to meet the clinical accuracy of AAMI SP10: 2002

Conclusions Drawn from Clinical and Nonclinical Testing

With the substantial testing of a non-clinical and clinical nature, it is the conclusion that the 750C is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2005

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

Re: K050844
Trade/Device Name: 750C Series Monitor
Regulation Number: 870.2700
Regulation Name: Pressure Regulator
Regulatory Class: II
Product Code: DQA, CCK
Dated: April 1, 2005
Received: April 12, 2005

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 (240) 276-0120. 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/industry/support/index.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 (if known): K050844

Device Name: 750C Series monitor

Indications for Use: The 750C monitor is intended to continuously calculate and display the following physiological vital signs: end tidal carbon dioxide, respiration rate, capnograph waveform, functional arterial oxygen saturation, pulse rate, plethysmograph waveform and an optional non-invasive blood pressure measurement of systolic, diastolic, mean arterial pressures along with pulse rate derived from a NIBP pressure waveform. The 750C is intended for monitoring of adult, pediatric and neonatal patients in the care of health care 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)

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

510(k) Number: K050844