May 8, 2015

CAS Medical Systems, Inc.
c/o Mr. Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K150620
Trade/Device Name: 740 SELECT
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: March 6, 2015
Received: March 10, 2015

Dear Mr. Ron 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please
contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041
or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note
the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part
807.97). For questions regarding the reporting of adverse events under the MDR regulation (21
CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office
of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the
Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)
796-7100 or at its Internet address

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
**Indications for Use**

510(k) Number: K150620

Device Name: **740 SELECT**

Indications for Use statement:

The 740 SELECT series of patient monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring, recording and alarming of multiple physiological parameters for use in adults, and pediatric patients.

The 740 SELECT series monitors come with multiple configurations and optional features. Standard and optional parameters include:

- Blood pressure and pulse rate;
- Functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate;
- Carbon Dioxide concentration of the expired and inspired breath and respiration rate including, with the Covidien Microstream MicroPod option, an Integrated Pulmonary Index (IPI);
- Electronic predictive and temporal artery temperature;
- ECG and heart rate derived from ECG;
- Impedance respiration to detect the rate or absence of respiratory effort with the ECG option for adult, adolescent, child and infant;
- Non-invasive monitoring, with Masimo Rainbow SET technology, of carboxyhemoglobin saturation (SpCO) and/or respiration (RRA). Other information displayed includes: Signal IQ Waveform, Low Signal IQ (Low SIQ), Perfusion Index (PI), and/or Pleth Variability Index (PVI) for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

Prescription Use  ✔ 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)
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

Address: 44 East Industrial Rd. Branford CT. 06405 USA

Contact: Ron Jeffrey – Director, Regulatory Affairs
Phone - (203) 488-6056
Fax – (203) 488-9438
Email – rjeffrey@casmed.com
Establishment Registration # 2244861

Prepared: March 6, 2015

Trade Name: 740 SELECT

Common Name: Monitor, Physiological, Patient

Classification Name: Cardiovascular Monitoring Device 870.2300 (MWI), Panel 74

Classification: Class II

Substantially Equivalent Device(s):

The 740 SELECT is equivalent to the following devices:

- CASMED 740 SELECT Monitor (K140430);
- Zoe Medical Nightingale Monitoring System (K130740)

DESCRIPTION

The 740 SELECT is a rugged portable non-invasive multi-parameter device used for spot checking or continuous monitoring of blood pressure, pulse rate, functional oxygen saturation (%SpO2), body temperature, etCO2, FiCO2 Respiratory rate derived from etCO2, ECG and Impedance Respiration in selected modes of operation.

The non-invasive blood pressure (NIBP) parameter automatically inflates an occluding cuff and,
using the oscillometric step-deflation measurement technique, determines systolic, diastolic and mean arterial pressure as well as pulse rate. Measurement results along with user prompts and error messages are displayed on the front panel. The frequency of NIBP determination can be elected by the user in times between one and ninety minutes. The auto (timed), STAT and manual NIBP operating modes provide additional clinical utility.

The pulse oximeter parameter (%SpO2) determines arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. The oximeter requires no routine calibration or maintenance. Oxygen saturation and heart rate are displayed on a light emitting diode (LED) digital display. On each detected pulse, the perfusion LED indicates patient perfusion signals. This bar graph gives the user a pulse-by-pulse visual indication of waveform signal quality. An audio “beep” can be enabled that is generated each time the SpO2 module detects a pulse. In addition to %SpO2 the 740 SELECT (equipped with the Masimo Rainbow® Pulse CO-Oximetry™ and Masimo SET ® oximetry) can monitor Pulse Rate (PR), Carboxyhemoglobin (SpCO®), Acoustic Respiration Rate (RRa™) and Pleth Variability Index (PVI®). Alternately, the customer can choose a Nellcor Pulse Oximeter at the time of ordering. The Nellcor Oximeter provides Response Mode and Sat Seconds.

The 740 SELECT has (2) options for measuring temperature. The Covidien™ FILAC 3000 predictive temperature parameter has the capability of taking temperature in either normal (predictive) or monitor mode. In the normal mode, the thermometer’s microprocessor “predicts” body temperature in about four (4) seconds for oral temperatures, about ten (10) seconds for axillary temperatures and about fifteen (15) seconds for rectal temperatures. The default setting used by the monitor for temperature determinations is the Predictive (normal) mode. Alternately, the customer can choose an Exergen Temporal Scanner™ (infrared) Thermometer at the time of ordering. The Exergen Temporal Scanner Thermometer, which captures core body temperature, has the capability of taking the Temporal Artery (TA) Temperature in about 3 seconds. The Exergen Temporal scanner has the ability to display the measurement of the patient’s core temperature in either °F or °C.

The 740 SELECT offers the optional choice of Sidestream and/or Mainstream etCO2 parameter monitoring. The customer choices for Sidestream CO2 monitoring are the Masimo - Phasein™ Infrared Sidestream Gas Analyzer (ISA™) or the Covidien Microstream® MicroPod™ which is integrated with the microMediCO2™ board. Customers may also choose Mainstream etCO2 parameter monitoring by using the Masimo Phasein™ infrared Mainstream Gas analyzer (IRMA™). Each of these CO2 options is externally attached to the SELECT.

This clearance adds the parameter ECG and Impedance Respiration.
The 740 SELECT Intended Use

The 740 SELECT series of patient monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring, recording and alarming of multiple physiological parameters for use in adults, and pediatric patients.

The 740 SELECT series monitors come with multiple configurations and optional features. Standard and optional parameters include:

- Blood pressure and pulse rate;
- Functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate;
- Carbon Dioxide concentration of the expired and inspired breath and respiration rate including, with the Covidien Microstream MicroPod option, an Integrated Pulmonary Index (IPI);
- Electronic predictive and temporal artery temperature;
- ECG and heart rate derived from ECG;
- Impedance respiration to detect the rate or absence of respiratory effort with the ECG option for adult, adolescent, child and infant;
- Non-invasive monitoring, with Masimo Rainbow SET technology, of carboxyhemoglobin saturation (SpCO) and/or respiration (RRa). Other information displayed includes: Signal IQ Waveform, Low Signal IQ (Low SIQ), Perfusion Index (PI), and/or Pleth Variability Index (PVI) for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

Technological Equivalence

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>740 SELECT (This submission)</th>
<th>740 SELECT (K140430)</th>
<th>Zoe Medical Nightingale (K130740)</th>
<th>How They Compare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use Statement and Device Parameters</td>
<td>The 740 SELECT series of patient monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring, recording and alarming of multiple physiological parameters for use in adults, and pediatric patients.</td>
<td>The 740 SELECT series of monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring and recording of:</td>
<td>The Zoe Medical Nightingale Monitoring System is indicated for use in adult &amp; pediatric patient populations. The Zoe Medical Nightingale Monitoring System facilitates the monitoring of:</td>
<td>The proposed 740SELECT utilizes the same Zoe Medical ECG component as the Nightingale Monitoring System predicate device. The remaining parameters and features in the proposed device were cleared in the</td>
</tr>
</tbody>
</table>

- Blood pressure and pulse rate of adult, pediatric and neonatal patients
- Functional oxygen saturation of arterial oxygen saturation (SpO₂)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>740 SELECT (This submission)</th>
<th>740 SELECT (K140430)</th>
<th>Zoe Medical Nightingale (K130740)</th>
<th>How They Compare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitors</td>
<td>hemoglobin (SpO2) &amp; pulse rate of adult, pediatric and neonatal patients</td>
<td>End-tidal &amp; inspired CO₂</td>
<td>The Zoe Medical Nightingale Monitoring System is a prescription device intended to be used by healthcare professionals in all areas of the healthcare facility.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Additionally the Masimo Rainbow SET technology provides noninvasive monitoring of carboxyhemoglobin saturation (SpCO) and/or respiration (RRa). Other information displayed on the 740 SELECT with the Masimo Rainbow SET option includes: Signal IQ Waveform, Low Signal IQ (Low SIQ), Perfusion Index (PI), and/or Pleth Variability Index (PVI) indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.</td>
<td></td>
<td>740 SELECT predicate under K140430.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Carbon Dioxide concentration of the expired and inspired breath and respiration rate of adult, pediatric, infant or neonatal patient and included, with the Oridion option, an Integrated Pulmonary Index (IPI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Intermittent predictive body temperature (oral, axillary, rectal) of adult, pediatric and neonatal patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Infrared (over the temporal artery) measurement of body temperature of people of all ages.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Waveforms</th>
<th>3</th>
<th>NA</th>
<th>3 or 5</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>User Interface</th>
<th>Touch Screen</th>
<th>Touch Screen</th>
<th>Push Knob and dedicated keys</th>
<th>The proposed 740SELECT uses a subset of the Zoe predicate device</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Display</th>
<th>7&quot; Color LCD</th>
<th>7&quot; Color LCD</th>
<th>8.4&quot; Color LCD</th>
<th>The 740SELECT is the same</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Operating Modes</th>
<th>Continuous</th>
<th>Continuous</th>
<th>Continuous</th>
<th>Same</th>
</tr>
</thead>
</table>
### Non-Clinical and Clinical Performance Testing to Demonstrate Substantial Equivalence

<table>
<thead>
<tr>
<th>Category</th>
<th>Testing Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Validation</td>
<td>Not applicable. The 740 SELECT (and predicates) are not and cannot be sterilized.</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>Not applicable. The 740 SELECT and provided accessories do not claim a shelf life.</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>The 740 SELECT and the provided accessories are claimed biocompatible by their manufacturers’ premarket notification.</td>
</tr>
<tr>
<td>Software</td>
<td>Software for the 740 SELECT (and predicates) was designed and developed in accordance with developer’s software development processes and has been verified and validated.</td>
</tr>
<tr>
<td>Electromagnetic Compatibility (EMC)</td>
<td>The 740 SELECT (and predicates) were tested for EMC in accordance with IEC 60601-1-2:2007 and comply with its predetermined specification.</td>
</tr>
<tr>
<td>Performance Testing – Bench</td>
<td>The 740 SELECT was tested in accordance with internal requirements and procedures, with test results indicating that the device complies with predetermined requirements.</td>
</tr>
<tr>
<td>Performance Testing – Animal</td>
<td>Animal performance testing was not performed for the proposed device or the predicate devices.</td>
</tr>
<tr>
<td>Performance Testing - Clinical</td>
<td>Clinical performance testing was not performed with the 740 SELECT for this submission. Clinical testing is not necessary to demonstrate safety and effectiveness.</td>
</tr>
</tbody>
</table>

### Table: Characteristic Comparison

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>740 SELECT (This submission)</th>
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<th>Zoe Medical Nightingale (K130740)</th>
<th>How They Compare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trends</td>
<td>1 minute to 4 hours</td>
<td>1 minute to 4 hours</td>
<td>72 hours</td>
<td>The 740SELECT is the same</td>
</tr>
<tr>
<td>Size</td>
<td>11” W x 7.63” H x 5.75” D</td>
<td>11” W x 7.63” H x 5.75” D</td>
<td>11.3” W x 7.2” H x 3.3” D</td>
<td>The 740SELECT is the same</td>
</tr>
<tr>
<td>Electrical</td>
<td>Medical grade power supply with internal lithium-ion battery</td>
<td>Medical grade power supply with internal lithium-ion battery</td>
<td>Medical grade power supply with internal lithium-ion battery</td>
<td>Same</td>
</tr>
<tr>
<td>Equipment Type</td>
<td>Portable, indoor use only</td>
<td>Portable, indoor use only</td>
<td>Portable, indoor use only</td>
<td>Same</td>
</tr>
<tr>
<td>Ingress Protection</td>
<td>IPX1</td>
<td>IPX1</td>
<td>IPX1</td>
<td>Same</td>
</tr>
<tr>
<td>Operating Conditions</td>
<td>0 to 40°C (32 to 104°F) 15 to 90% RH, non-condensing 0 to 15,000 ft</td>
<td>0 to 40°C (32 to 104°F) 15 to 90% RH, non-condensing 0 to 15,000 ft</td>
<td>0 to 40°C (32 to 104°F) 15 to 90% RH, non-condensing 0 – 15,000 ft</td>
<td>Same</td>
</tr>
<tr>
<td>Storage Conditions</td>
<td>-20 to 60°C (-4 to 140°F) 15 to 95% RH, non-condensing 0 to 40,000 ft</td>
<td>-20 to 60°C (-4 to 140°F) 15 to 95% RH, non-condensing 0 to 40,000 ft</td>
<td>-20 to 60°C (-4 to 140°F) 15 to 95% RH, non-condensing 0 to 40,000 ft</td>
<td>Same</td>
</tr>
</tbody>
</table>
Conclusions Drawn from Clinical and Non-Clinical Testing

With the addition of ECG and Impedance Respiration as the only change from the previous 740 SELECT clearances, it has been determined that the 740 SELECT is substantially equivalent to the predicate device(s).