

K061557

Section 2. SUMMARY AND CERTIFICATION

SEP 15 2006

A. 510(K) SUMMARY

A.1 Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Medwave, Inc. summary for the Vasotrac® APM205A System.

SUBMITTER'S NAME: Medwave, Inc.
 ADDRESS: 4382 Round Lake Road West
 St. Paul, MN 55112
 CONTACT PERSON: Donna R. Lunak
 TELEPHONE NUMBER: 651-639-1227
 FAX NUMBER: 651-639-1338
 DATE OF SUBMISSION: 05/22/06

A.2 Identification Of Device

Proprietary Name: Fusion™

Common Name: Patient Monitor

Classification Status: Class II

| | |
|---|----------|
| Non-invasive blood pressure measurement | 870.1130 |
|---|----------|

| | |
|--|----------|
| Module Option Oximeter Tyco Healthcare, Nellcor Oximax (K012891) | 870.2700 |
|--|----------|

| | |
|---|----------|
| Module Option Clinical Electronic Thermometer Tyco Healthcare, Kendall Genius Thermometer (K920713) | 880.2910 |
|---|----------|

A.3 Equivalent Devices

Medwave, Inc. believes the Fusion™ System is substantially equivalent to Medwave, Inc. Vasotrac® APM2052A System (K011152).

A.4 Description of the Device

The Fusion™ System is a non-invasive blood pressure monitor that uses a pressure sensor placed directly on top of the radial artery. This sensor is noninvasive and eliminates the need for an occlusive inflatable cuff. This device is intended to be used on patients by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure, and pulse rate.

The Fusion™ System uses a patented "sweep technique" which applies a varying force on the radial artery. The counterpressure in the artery produces a signal which is digitized and used to calculate blood pressure parameters.

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Description of the Device (continued)

The sensor measures the pulse at the point of maximum energy transfer; the wave shapes are analyzed by Medwave's proprietary algorithms. Parameters are

extracted from the waveforms and a set of coefficients are applied to them yielding systolic, mean, and diastolic pressures approximately every 15 heart beats. These algorithms have been tested and validated in clinical studies by synchronized comparisons to arterial line pressure waveforms.

Patient pressures can be monitored visually by viewing the screen and audibly entering limits into the Fusion™ System alarm menu. Patient measurements above or below the limits will be automatically brought to the attention of the caregiver through these visual and audible alarms. A Start/Stop key provides the operator with an option to cancel operation at anytime.

The Fusion™ System can be ordered with additional module options:

- Tyco Healthcare Nellcor OxiMax Pulse Oximetry System (K012891) provides monitoring of a patient's functional oxygen saturation of arterial hemoglobin.
- Kendall Genius Thermometer (K920713) provides patient's body temperature readings.
- Seiko Thermal Printer SII providing hardcopy of readings selected to print.

A.5 Intended Use

The Fusion™ System and accessories blood pressure measurement system is intended to be used on patients with wrist circumference of 11 cm – 22 cm by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate.

The Fusion System with the Nellcor OxiMAX Option is indicated for the continuous non-invasive monitoring of a patient's functional oxygen saturation of arterial hemoglobin (SpO2) by trained medical personnel.

The Fusion System with the Kendall Genius Thermometer (K920713) is indicated for the measuring of a patient's body temperature.

This device is prescription use only.

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A.6 Technological Characteristics, Comparison to Predicate Device.

Like the predicate device, the Fusion™ System is a non-invasive blood pressure monitor, which uses a pressure sensor placed on the wrist over the radial artery. This device is intended to be used on patients by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate. The information from this device is intended to guide clinicians in the therapeutic management of their patients by: providing accurate and frequently updated blood pressure information in a safe, non-invasive, easily obtained, and comfortable manner. Both the devices measure the diastolic, systolic blood pressure and pulse rate from the wrist using oscillometric methods. Both the devices are microcomputer controlled.

Like the Vasotrac® System (K011152), the Fusion™ System have a memory function that retains approximately 900 readings.

Like the Vasotrac® System (K011152), the Fusion™ System display systolic, diastolic blood pressures ranging from 40 and 240 mmHg. Both systems have a blood pressure measurement accuracy of a mean difference of ± 5 mmHg or less with a standard deviation of 8mmHg or less. The pulse measurement range is the same for both the Vasotrac® System (K011152) and the Fusion™ System, from 40 – 200 bpm. The accuracy of the pulse measurements are ± 5 bpm or 10% of the measured pulse frequency.

(Supported by study results in the supporting Clinical Data on file at Medwave, Inc.)

Both Vasotrac® System (K011152) and the Fusion™ utilize the application of pressure to the artery (by the sensor); the counter pressure in the artery produces a pressure waveform. When maximum amplitude is achieved, mean blood pressure is calculated. The Vasotrac® System (K011152) and the Fusion™ System use a unique “sweep” technique for applying pressure to a the radial artery: downward pressure is applied by the sensor to the radial artery at a rate of ~ 10 mmHg per heart beat increasing as the beat amplitude increases and decreasing rapidly when the beat amplitude begins to decrease. A curve fit is made using the amplitude of each beat versus the hold down pressure to form the bell shaped curve. This curve fit is used to determine the true peak that might occur between pulses as well as to filter out small variations due to artifacts or aberrancies.

Both the Vasotrac® System (K011152) and the Fusion™ System utilize Medwave’s proprietary algorithms in analyzing the pressure waveforms to calculate the systolic, mean and diastolic readings. Parameters are extracted from the waveforms and a set of coefficients is applied to them, yielding systolic, mean and diastolic pressures. The algorithms have been tested against intra arterial line pressure waveforms and proven to meet industry standards set by the American Medical Instrumentation (AAMI), mean difference of $+ 5$ mmHg or less with a standard deviation of 8mmHg or less.

(Supported by study results in the Clinical Data on file at Medwave, Inc.)

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The Vasotrac® System (K011152) and the Fusion™ System software are identical with the exception of insignificant features incorporated.

The Vasotrac System (K011152), as the Fusion™ System, has a power switch and a LCD display. The operating environment of 10⁰C – 40⁰C and 10% to 90% relative humidity.

The Fusion™ and the predicate device - the Vasotrac® APM205A Noninvasive Blood Pressure Measurement System (K011152) use the same non-invasive blood pressure measurement accessories.

Any minor differences in the appearance, technology, or manufacture of the predicate device and the Fusion™ System do not raise any new questions of safety or effectiveness. Associated risks posed by the Fusion™ System are thought to be no more than those of well-designed automated cuff-based noninvasive blood pressure devices currently marketed in the interstate commerce are. Both the device and the sensor have been designed to minimize the risk to patients from burns, excessive pressure or sensor failure caused by either normal device use by patient and/or clinical abuse.

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A.7 Discussion of Performance Testing

An extensive collection of tests has been conducted and successfully completed. Summary follows:

| Requirements | ANSI/AAMI SP10-2002 American National Standards for Electronic or Automated Sphygmomanometers | IEC60601 | Center For Devices And Radiological Health Noninvasive Blood Pressure Monitor Guidance Document | Other As Listed |
|---|---|--------------|---|-----------------|
| Device Labeling | X | X | X | ----- ---- |
| Outer Container Labeling | X | X | X | ----- ---- |
| Information Manual | X | X | X | ----- ---- |
| Component Labeling | X | X | X | ----- ---- |
| Power System Labeling | X | ---- | X | ----- ---- |
| Storage Conditions – 20°C (-40°F) – 50°C (122°F) | X | ---- | ----- | ----- ----- |
| Operating Temperature Conditions 10°C (50°F) – 40°C (104°F) | X | ---- | ----- | ----- ----- |
| Operating Humidity Conditions 15 – 90 percent (noncondensing) | X | ---- | ----- | ----- ----- |
| Operating Range in Altitude Conditions -170 to 1700 meters (-500 to 5000 feet), referenced to sea level | X | ---- | ----- | ----- ----- |
| Vibration and Shock | ----- | ----- -- | ----- | NSTA |
| Voltage Range | N/A | N/A | N/A | N/A |
| Life test minimum of 10,000 full scale cycles | X | ----- --- | ----- | ----- ---- |
| Maximum cuff pressure | N/A | N/A | N/A | N/A |
| Cuff deflation | N/A | N/A | N/A | N/A |
| Electrical safety | ----- | X | ----- | IEC601 |
| Conductive components | ----- | X | ----- | ----- ---- |
| Pressure indicator accuracy | X | ----- --- | ----- | ----- ---- |
| Overall system efficacy | X | ----- - | ----- | ----- ---- |
| Auscultatory method as the reference standard | N/A | N/A | N/A | N/A |
| Intraarterial method as the reference standard | X | ----- --- | ----- | ----- ---- |

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| Requirements | ANSI/AAMI SP10-2002 American National Standards for Electronic or Automated Sphygmomanometers | IEC60601 | Center For Devices And Radiological Health Noninvasive Blood Pressure Monitor Guidance Document | Other As Listed |
|--|---|--------------|---|---------------------|
| Battery indicator | N/A | ----- --- | ----- | ----- |
| Requirements for devices with manual inflation | N/A | N/A | N/A | N/A |
| Comparison Testing | N/A | N/A | N/A | N/A |
| Foreign Standards | N/A | N/A | N/A | N/A |
| Software Testing | ----- | ----- --- | ----- | Medwave 795-0000 |
| Electromagnetic Compatibility | ----- | X | ----- | ----- |
| Biocompatibility | ----- | ---- | X | ----- |
| Sterilization | N/A | N/A | N/A | N/A |
| Packaging | N/A | N/A | N/A | N/A |
| Shelf Life | N/A | N/A | N/A | N/A |

A.8 Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Medwave, Inc. that Fusion™ is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

Medwave, Inc.
c/o Ms. Donna R. Lunak
VP of Regulatory Affairs
4382 Round Lake Road West
Arden Hills, MN 55112

Re: K061557

Trade Name: Fusion™ System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 14, 2006
Received: August 23, 2006

Dear Ms. Lunak:

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Bram D. Zuckerman".

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 (if known): K061557

Device Name: Fusion™ System

Indications for Use:

The Fusion™ System and accessories blood pressure measurement system is intended to be used on patients with wrist circumference of 11 cm – 22 cm by trained medical personnel to continually monitor systolic, diastolic and mean blood pressure and pulse rate.

The Fusion System module option of Nellcor OxiMAX Option (K012891), is indicated for the continuous non-invasive monitoring of a patient's functional oxygen saturation of arterial hemoglobin (SpO2) by trained medical personnel.

The Fusion System module option of Kendall Genius Thermometer (K920713) is indicated for the measuring of a patient's body temperature.

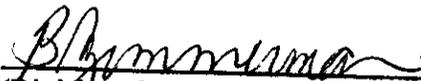
This device is prescription use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061557