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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Medwave, Inc. summary for the Primo™.

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:	11/14/05

1. Identification of device

Proprietary Name: Primo ™
Common Name: Wrist Sphygmomanometer
Classification Status: Class II per regulations 870.1130 Product Codes

2. Equivalent devices

Medwave, Inc. believes the Primo ™ Noninvasive Blood Pressure Measurement System is substantially equivalent to Medwave, Inc. Vasotrax® Portable Wrist Noninvasive Blood Pressure Measurement System (K001898).

3. Description of the device

The Primo ™ Noninvasive Blood Pressure Measurement System is a hand-held non-invasive blood pressure measurement system that measure systolic, diastolic blood pressure and pulse rate from the user's wrist. The system is contained in hard plastic housings that contain a user interface panel and a wrist sensor. The characteristics of the arterial waveforms are recorded with a unique pressure sensor that is placed over the radial artery. This system provides a single reading of blood pressure, using a pressure sensor placed on the wrist over the radial artery. This sensor is noninvasive.

4. Intended Use

The Medwave, Inc. Primo ™ Noninvasive Blood Pressure Measurement System is a hand held non-invasive blood pressure measurement system intended to be used on adult patients with wrist circumferences of 11 cm – 22 cm by trained medical personnel to measure systolic, diastolic blood pressure and pulse rate.

5. Technological characteristics, comparison to predicate device.

Like the predicate device, the Primo ™ Noninvasive Blood Pressure Measurement System measures the diastolic, systolic blood pressure and pulse rate from the wrist using oscillometric methods. Both the Primo ™ Noninvasive Blood Pressure Measurement System and the Vasotrax® Portable Wrist Noninvasive Blood Pressure Measurement System (K001898) are microcomputer controlled.

Like the Vasotrax® Portable Wrist Noninvasive Blood Pressure Measurement System (K001898), the Primo™ Noninvasive Blood Pressure Measurement 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 ± 5mmHg or less with a standard deviation of 8mmHg or less. The pulse measurement range is the same for both the Primo™ Noninvasive Blood Pressure Measurement System and the Vasotrax® Portable Wrist Noninvasive Blood Pressure Measurement System (K001898), 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 Primo ™ Noninvasive Blood Pressure Measurement System and the Vasotrax® System (K001898) 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 Primo ™ Noninvasive Blood Pressure Measurement System and the Vasotrax® System (K001898) 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 ~10mmHg 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.

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Technological characteristics, comparison to predicate device (continued)

Both the Primo Noninvasive Blood Pressure Measurement System and the Vasotrax® (K001898) utilize Medwave's proprietary algorithms in analyzing the pressure waveforms to calculate the systolic and diastolic readings. Parameters are extracted from the waveforms and a set of coefficients is applied to them, yielding systolic 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 $\pm$ 5mmHg or less with a standard deviation of 8mmHg or less.
(Supported by study results in Appendix H)

The Primo ™ Noninvasive Blood Pressure Measurement System, as well as the Vasotrax ® System (K001898) has a power switch and a display. The operating environment of 10^0C – 40^0C and 10% to 85% relative humidity. Both the Primo System and the Vasotrax ® Portable Wrist Noninvasive Blood Pressure Measurement System (K001898) are battery powered. Any minor differences in the appearance, technology, or manufacture of the Primo ™ Noninvasive Blood Pressure Measurement System device and the predicate device do not raise any new questions of safety or effectiveness. Associated risks posed by the Primo ™ Noninvasive Blood Pressure Measurement System are thought to be no more than those of a well designed automated cuff-based noninvasive blood pressure devices currently marketed in the interstate commerce. Both the device and the sensor have been designed to minimize the risk to patients from excessive pressure or sensor failure caused by either normal device use by the caregiver and/or clinical abuse.

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6. 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	X	----------
Storage Conditions – 20°C (-40°F) – 50°C (122°F)	X	X	----------	----------
Operating Temperature Conditions 10°C (50°F) - 40°C (104°F)	X	X	----------	----------
Operating Humidity Conditions 15 90 percent (noncondensing)	X	X	----------	----------
Operating Range in Altitude Conditions - 170 to 1700 meters (-500 to 5000 feet), referenced to sea level	X	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	----------	----------	----------

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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
Auscultatory method as the reference standard	N/A	N/A	N/A	N/A
Intraarterial method as the reference standard	X	----------	----------	----------
Battery indicator	X	----------	----------	----------
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 795-0092, 795-0094
Electromagnetic Compatibility	----------	X	----------	----------
Biocompatibility	----------	----	X	ISO10993 -1-
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

7. **Conclusion**

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2006

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

Re: K053185
Trade Name: Primo™ Noninvasive Blood Pressure Measurement System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 14, 2005
Received: November 14, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman 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 (if known): K053185

Device Name: Primo™

Indications For Use:

The Primo™ Noninvasive Blood Pressure Measurement System is a hand held non-invasive blood pressure measurement system intended to be used on adult patients with wrist circumferences of 11 cm – 22 cm by trained medical personnel to measure systolic and diastolic blood pressure and pulse rate.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053185