DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

CNSystems Medizintechnik GmbH
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K014063
Trade Name: Task Force® Monitor 3040
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: January 31, 2002
Received: January 31, 2002

Dear Mr. Job:

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.

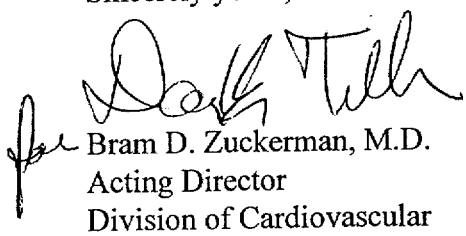
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

Enclosure

510(k) Number (if known): K014063

Device Name: **Task Force® Monitor 3040**

Indications For Use:

The Task Force® Monitor 3040 (TFM) is intended to noninvasively measure and display a patient's hemodynamic parameters using Impedance Cardiography (ICG), Electrocardiography (ECG), oscillometric Blood Pressure (oscBP) and continuous Blood Pressure (contBP). The TFM monitors continuously the subject's hemodynamic parameters without reporting any diagnosis. Every measurement must be supervised by a medical trained professional. The Task Force® Monitor 3040 is a diagnoses aiding device and therefore not designed for vital sign monitoring or self-monitoring of patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014063

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1. Summary and Certification

1. 1 Premarket Notification 510(k) Summary

SUBSTANTIAL EQUIVALENCE
Identification of predicate devices, model and manufacturer:

Predicate device:	CardioDynamics BioZ.pc
Model:	BZ-500/BZ-501
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K001081
Reason for Submission:	New device

Predicate device:	Ohmeda Finapres
Model:	2350 Finapres
Manufacturer:	Ohmeda Medical
Predicate Device 510(k):	K880572
Reason for Submission:	New device

The Task Force® Monitor 3040 is substantially equivalent to the BioZ.pc in terms of design, intended use and principle of operation. Furthermore the Task Force® Monitor 3040 is substantially equivalent to the Finapres 2350 in terms of intended use and principle of operation.
The Task Force® Monitor 3040 simply combines the noninvasive hemodynamic patient monitoring principle of the BioZ.pc system with the noninvasive continuous blood pressure measurement of the Finapres 2350 device. The patient instrumentation electronics (which provides all data acquisition, isolation and defib protection) are separated from the PC which interacts with the user. The software is pre-installed on the PC, a backup copy of the software is enclosed.

The software of the Task Force® Monitor 3040 controls the hardware, displays the hemodynamic parameters and gives the user the possibility to store the measurement data on the hard disk (like the BioZ.pc). Both devices (Task Force® Monitor 3040 and BioZ.pc) use a software integrity check when the monitoring software is first activated, to insure that no corruption has occurred of any of the operation software used by the device. Furthermore the TFM repeats this check at the beginning of each measurement.

A difference is the software installation kit: while CardioDynamics encloses a software installation kit diskette, the TFM software is pre-installed on the PC. Furthermore Cardiodynamics allows only particular models of notebook PC's which have been previously validated by CardioDynamics, due to the short life cycle of state-of-the-art PC's, CNSystems ships a fully tested PC with the TFM system.

The Task Force® Monitor 3040, the BioZ.pc system and the Finapres device are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of the Task Force® Monitor 3040 is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG) and continuous blood pressure (contBP) measurement. Monitoring is accom-

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plished by attaching 3 double electrodes and a neutral electrode for ICG (1 in the neck and 2 on each side of the thorax), 4 electrodes for ECG, one finger cuff for continuous blood pressure measurement and one upper arm cuff for oscillometric blood pressure measurement. ICG is injecting a minimal current through the upper electrodes and reading the returning voltage waveform from the inner electrodes.

The Task Force® Monitor 3040 uses the same methods and algorithms for calculating the patient's hemodynamic parameters as both predicate devices.

Blood pressure is measured in two ways: the absolute blood pressure values are measured with an oscillometric device and the continuous blood pressure changes are measured with the contBP (same method as the Finapres device). The TFM system automatically corrects the continuous blood pressure trend to the absolute values of the oscillometric device. Due to the state-of-the-art electronic components, the blood pressure is monitored contiguously without any interruptions while the Finapres device has to interrupt the measurement for resetting the set point from time to time.

Both the Task Force® Monitor 3040 and the BioZ.pc are IBM PC-based products, which differ only in the version of the operation system.

The Task Force® Monitor 3040 (TFM) is substantially equivalent to its predicate devices, the BioZ.pc currently marketed by CardioDynamics International Corporation and the Finapres 2350. The TFM has the same intended use and no technological differences which would rise new questions concerning safety and effectiveness.

The justification for this substantial equivalence determination is presented below.

Substantial equivalence is shown in the following table (on the next page).

JRH

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Substantial Equivalence

Table

Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
Manufacturer	CNSystems Medizintechnik GmbH Baumkircherstrasse 1 A - 8020 Graz, Austria	CardioDynamics International Corp. 6175 Nancy Ridge Drive San Diego, CA 92121, USA	Ohmeda Medical 355 Inverness Dr. South Englewood, CO 80112 5810, USA
510(k) number	none	K001081	K880572
Indication for use	The TFM has the same intended use/indications for use as the BioZ.PC device. Additionally it combines the ICG method and the continuous blood pressure method of the Finapres device.	The device is for use in the hospital, outpatient and clinical setting. The BioZ.PC is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG). Monitoring is accomplished by attaching 8 electrodes to the patient, injecting a minimal current through the upper electrodes, and reading the returning voltage waveform from the inner electrodes. Each measurement has to be supervised by a medical professional.	The Finapres device is to noninvasively and continuously measure a patient's arterial blood pressure using the photoplethysmographic method first described by Penaz. The device uses a finger cuff for systolic and diastolic blood pressure measurement and calculates also mean arterial blood pressure.

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Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
Physical description / functioning	The device architecture of the TFM is equivalent to the BioZ.pc. The TFM system consists of a Patient Biosignal Electronic System (PBES) and a PC for calculating and displaying the hemodynamic parameters. ICG signals from a patient are assessed using the same method as the predicate device (8 electrodes, injecting a minimal current). The user inputs the patient's data into the TFM software on the PC including gender, age, height, weight, hematocrit and the distance between the inner ICG electrodes. The PC runs Windows 2000 operating system. The parameters are displayed on a full color screen and measurement data can be stored on the PC's hard disk. The TFM calculates and displays the same hemodynamic parameters as the predicate device.	The device consists of a Patient Interface Module and a separate PC. The PC software provides the user interface for the BioZ.pc system and checks the hardware when the software is activated. The user inputs patient parameters into the user software, including patient gender, height, body frame size, weight, age and blood pressure. The Monitor then utilizes these parameters and measures the ICG signals to determine the hemodynamic properties of that particular patient. The PC runs Windows 98 operating system. The parameters are displayed on a full color screen and measurement data can be stored on the PC's hard disk.	This device measures noninvasively arterial blood pressure in the finger using a method originally devised ba Dr. Jan PENAZ. The monitor displays the pressure wave form, digital values of systolic, diastolic and mean pressure as well as pulse rate and a time annotated trend display. The device uses a cathode ray tube (CRT) for displaying the signals and values. To follow the arterial blood pressure the Finapres has a servo valve to control the cuff pressure, the pressure transducer are located in the patient interface module. The finger cuff contains the photo electronic components for measuring a blood Plethysmograph and a bladder for applying pressure to the finger. The bladder is wrapped around the patient's finger and connected to the patient interface module. A pump in the monitor unit provides the finger cuff with required air pressure.

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Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
	A difference between the TFM and the BioZ.pc is the blood pressure measurement. The predicate device uses manual user input of blood pressure values or optional an oscillometric BP measurement. The interval of measurement can be set by the user. The TFM system includes the continuous blood pressure method of the Finapres device for assessing online and real-time blood pressure values.	Monitoring is accomplished by attaching 8 electrodes to the patient, injecting a minimal current through the upper electrodes, and reading the return voltage waveform from the inner electrodes. The device calculates and displays 12 hemodynamic parameters including Stroke Volume (SV), Cardiac Output (CO), System Vascular resistance, Velocity Index (VI), Thoracic Fluid Content (TFC), Systolic Time Ratio, Left Ventricular Ejection Time (LVET), Pre-Ejection Period (PEP), Left Cardiac Work/Index (LCWI), Heart rate (HR), Systolic and Diastolic Blood Pressure (SBP, DBP). Each PC provided will be fully tested with its BioZ.pc device prior to shipment.	

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	The Penaz-method for beat-to-beat blood pressure measurement (same as the Finapres device) follows very good the arterial blood pressure trend but the absolute values of BP are not accurate due the physiology of finger arteries. Therefore TFM uses a oscillometric blood pressure device for assessing absolute BP values and continuos BP for trend recording. A difference between the TFM and the Finapres device is the interruption of measurement. While the Finapres interrupts from time to time for re-setting the pressure set point, the TFM has no interruptions because of state-of.the-art electronic components. A clinical study shows, that both devices follow the arterial blood pressure very well with the difference, that the TFM has no interruptions in the signal. Because of the combination of ICG and continuous BP further analysis can be made: spectra of blood pressure variability and Baroreceptor Reflex Sensitivity (BRRS). Both methods have been published many times.		

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	Each TFM system is pre-installed and fully tested prior to shipment.		
Patient Circuitry Package	Internal to TFM instrument	Internal to BioZ.PC instrument	Internal to Finapres instrument
CPU	Intel Pentium III of higher	Intel 586 or equivalent	none
CPU Packaging	External PC	External PC	none
PC Operating System	Windows® 2000	DOS within Windows®98	none
PC Software	Pre-installed and fully tested on every TFM prior to shipment.	Provided on a CD-ROM	none
User Interface Software	TFM program V1.1 Revision 3	BioZ ver 1.52	not known
User Display	External PC VGA Screen	External PV VGA Screen	Internal cathode ray tube (CRT)
Blood Pressure Electronics	Internal to TFM instrument	Internal to BioZ.PC instrument	Internal to Finapres instrument

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Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
Performance specification	**ICG** measuring current: 400µA eff., 40 kHz, temporal derivative of impedance dZ/dt: ±10 Ohm/s **ECG** measuring range ±5mV, indication range 30 - 150 beats/min, sampling frequency: 1000Hz (Europe), 1200Hz (USA) **oscillometric BP** measuring accuracy: ±5mmHg, measuring range: 50 to 250mmHg **continuous BP** measuring accuracy: ±5mmHg (due to oscBP), measuring range: 50 to 250mmHg The inaccurateness of the ICG signal can raise under following conditions: * sepsis * severe heart insufficiency * aortic valve insufficiency * aortic valve stenosis *patient movement artefacts	**ICG** measuring current: 2.5mA rms, 70kHz, no further information available; **ECG** sampling frequency: 1000Hz (in Europe) The device does not accommodate patients who: * weight more than 340 lb. (164 kg) * weight less than 60 lb. (27.3 kg) have mean arterial pressure greater than 130mmHg * have late sepsis (e.g., stage 3 and 4) * have aortic insufficiency	**BP** measuring range: 20 to 260mmHg, measuring accuracy: pressure transducer Linearity: + 2mmHg to -4.5mmHg (+ 0.25kPa to - 0.55kPa **Heart rate** measuring range: 12 to 175bpm, measuring accuracy: ± 5bpm or ± 5% of reading, whichever is higher

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	The inaccurateness of the oscillometric blood pressure signal can raise under following conditions: * weak pulses * irregular pulses * patient movement artefacts * tremor artefacts * respiratory artefacts * gravel road artefacts The device does accommodate patients within the following limits: * weight: 66.14 - 440.9 lbs (30 - 200 kg) * height: 1.64 - 8.20 feet (50 - 250 cm)		
Power Consumption	**115V version** nominal voltage: 115V / 60Hz power consumption: 240mA, 25W **230V version** nominal voltage: 230V / 50Hz power consumption: 120mA, 25W	115V / 60Hz 230V / 50Hz	**115V version** nominal voltage: 115V / 60Hz power consumption: 1,5A **230V version** nominal voltage: 230V / 50Hz power consumption: 0,75A

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Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
Dimensions / weight	**Main monitor** (height x width x depth) 4.13in x 18.31in x 11.42in (10.5cm x 46.5 cm x 29cm) **Continuous device** (height x width x depth) 1.38in x 3.31in x 6.46in (3.5cm x 8.4cm x 16.4cm) **Oscillometric device** (height x width x depth) 1.38in x 3.15in x 5.12in (3.5cm x 8cm x 13cm) **Weight** (including all TFM devices and cables without PC and screen: 15.4 lbs (7 kg)	Dimensions (width x height x depth) 14.0in x 12.1in x 7.0in (35.6cm x 30.8cm x 17.8cm) weight: 12 lbs (5.5kg)	**Monitor unit** (height x width x depth) 6.1in x 11.8in x 16.7in (15.5cm x 30cm x 42.5cm) **Patient Interface Module** 1.63in x 2.75in x 3.9in (4.14vm x 6.98cm x 9.9cm) Weight: 26.2 lbs (11.9 kg)

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Materials / Accessory	**Patient cables:** 8.2 ft. (2.5 m) **Electrodes:** all disposable electrodes are for single use, tested and certified according to ISO 10993-1 **ICG:** 4 electrodes * Polyethylene foam plastic with a medical adhesive made of polyacrylate * composite film made of 38µm polyester film and 12µm aluminium film * the electro conductive adhesive consists of polyacrylate, polyole, water and electrolyte *the electrodes are latex free and PVC free **ECG:** 4 electrodes (510(k) number: K853939) *polyethylene foam plastic, 1mm with a medical adhesive made of polyacrylate * sensor system: the stud (upper part) is made of stainless steel, the eyelet (lower part) is made of ABC plastics with 0,0025mm Ag/AgCl-coating * a quick-recovery conductive gel containing 3% KCl * a little sponge drenched in gel	Patient cable: 10ft (3m) Electrodes: Four Pre-Gelled, Disposable Dual Sensors	Patient cable: 16ft (5m) Finger cuff: plastic material

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	* a label made of polyethylene * the cover foil is made of polyethylene, 40 - 70µm * the cover for the sponge is made of polyethylene The ECG electrodes are latex free. **Finger cuff and fixing cuffs:** The fabric is tested according to ISO 10993 and is used by Borch Textile Group for their Surgical Gowns (FDA 510(k): K954674). **Oscillometric cuff:** The TFM uses BP cuffs from Rudolf Riester GmbH & Co. KG, Jungingen, Germany. These cuffs are generally used by Riester BP devices (for example K002954)		

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Attribute	Task Force Monitor 3040 (new)	BioZ.PC (Predicate)	Ohmeda 2350 Finapres (Predicate)
Standards	* IEC 60601-1, Medical electrical equipment, General requirements for safety * IEC 60601-1-1, 1. Collateral Standard: Safety requirements * IEC 60601-1-2, 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests * IEC 60601-1-4, 4. Collateral Standard: Programmable electrical medical systems * IEC60601-2-25, Part 2: Particular requirements for the safety of electrocardiographs * IEC 60601-2-30, Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment. * EN 1060-1, Non-invasive sphygmomanometers - Part 1: General requirements * EN 1060-3, Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems * ANSI/AAMI SP 10, Electronic or automated sphygmomanometers * ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing	* IEC 601-1 * UL2601 * CSA 622.2	