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Section E – 510(k) Statement and Summary

Premarket Notification 510(k) Summary

SUBSTANTIAL EQUIVALENCE:
Identification of predicate devices, model, and manufacturer:

Predicate device 1:	CardioDynamics BioZ.pc
Model:	Part # BZ-500/501
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K001081 on 6/31/2000
Reason for Submission:	Repackaging and porting of functionality from an off-the-shelf PC platform to a Philips cardiograph for the user display and interface. Use of BioZDx ported software and change of operating system from Windows™ to Windows CE™. Improvements to patient cable including enhanced defib protection, and removable/replaceable left and right interconnect assemblies. Built-in rather than externally attached printer.

Predicate device 2:	CardioDynamics BioZ.com
Model:	Part # BZ-4110
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K974725 on 3/18/1998
Reason for Submission:	Repackaging and porting of functionality from an embedded PC platform to a Philips cardiograph for the user display and interface. Use of BioZDx ported software and change of operating system from Microsoft DOS 6.22 to Windows CE™. Improvements to patient cable including enhanced defib protection, and removable/replaceable left and right interconnect assemblies. . Built-in rather than externally attached printer.

The BioZDx Hemodynamic Monitor is substantially equivalent to its predicate devices, the BioZ.pc System and the BioZ.com System currently marketed by CardioDynamics International Corporation. The justification for this substantial equivalence determination is presented below.

The BioZDx Hemodynamic Monitor is substantially equivalent to the BioZ.pc System in terms of design, intended use and principles of operation. The BioZDx Hemodynamic Monitor simply re-packages and re-partitions the electronics of the product for the convenience of users who wish to have an integrated solution including a built-in printer which provides reports on standard ECG 8-1/2 x 11 grided paper.

The BioZDx has nearly identical DSP software structure to the predicate devices, with enhanced fiducial point detection techniques over those used in the predicate devices, and the addition of a statistical based modulation factor for dZ/dT_{max} rather than the empirical technique employed in the predicate devices. There were no unexpected test results due to these changes and the validation of these changes is included in Section J.

The user software has been simplified compared to either of the predicate devices and ported from DOS 6.22 running under Microsoft Windows to Microsoft Windows CE to take advantage of the features of the new user platform.

The new user platform is the hardware and core operating system software of the Philips PageWriter Trim Cardiograph, 510(k) K031422 on 7/3/2003, less the ECC-specific hardware and ECG application software. The Philips ECC-specific hardware and ECG application software have been replaced with their equivalent ICG counterparts.

The User Software which provides the user interface for the BioZDx system is loaded onto the PC using a software installation kit, similar to the method used for the predicate device. The predicate device used a floppy disk or an attached notebook PC for software installation. The BioZDx uses a pre-programmed PCMCIA flash memory card.. Both devices store the user software on the internal storage of the user platform component of the system. Both products use an identical software integrity check when the monitoring software is first activated, to insure that no corruption has occurred of any of the operating software used by the device.

The BioZDx provides a printed report as do the two predicate devices. In the BioZDx, the printer is internal to the device rather than attached externally. The report in the BioZDx contains the same information as the predicate devices, but is reformatted to standard grid ECG paper. Both the predicate devices and theBioZDx use the HPGL graphic language for formatting printouts and communication with the print engine.

The BioZDx product also includes an improved patient cable, with enhanced defib protection and removable/replaceable left and right distal interconnect sections. The defib protection components are identical to those used in the predicate devices, but they are moved to the patient cable yoke and closer to the patient. The distal patient cable sections also include identification chips to prevent users from operating the device with unapproved and unvalidated cable systems. All final product testing was performed with prototype versions of the improved patient cable.

CardioDynamics International Corporation has labeled the version of BioZDx software clearly on the installation kit flash memory card. The installation instructions in the kit, and the user manual instructions for use clearly specify the kit only for use with the BioZDx product.

Both BioZ.pc and the BioZ.com predicate devices as well as the new BioZDx systems are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of the BioZDx (identical to the predicate device) is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG). Monitoring is accomplished by attaching 8 electrodes to the patient (two dual electrodes on each side of the neck and thorax), injecting a minimal current through the upper electrodes, and reading the returning voltage waveform from the inner electrodes.

The BioZDx Hemodynamic Monitor utilizes CardioDynamics' proprietary DSP electronic circuitry and software incorporating formulas and algorithms to calculate the various hemodynamic parameters. The user inputs patient parameters into the user software, including patient gender, body frame size, height, 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 patient interface circuitry (which provides all data acquisition, processing, and isolation) is similar to the predicate devices, and tested to the same internal and Agency specifications All changes to the new product from the predicate device are verified and validated within the body of hardware and software testing. The validation reports are included in Section J for System, Hardware, and Signal Processing, and Section M for software.

The ICG electrodes (BioZTect Sensor) to be used with the BioZDx device are sold separately, and are identical to those marketed for use with both the BioZ.pc and BioZ.com predicate device products. The BioZTect Sensor received 510(k) Clearance (K011797) on 7-3-2001.

The predicate devices (the BioZ.pc and the BioZ.com) and the new BioZDx Hemodynamic Monitor are IBM PC Family (Intel Pentium-class core processor-based) products, which differ primarily in partitioning and packaging. Both utilize Microsoft operating systems, either alone or within a Windows or Windows CE environment.

The predicate devices required the use of an external simulator device (the CardioDynamics BZ-4525 BioZ.sim device) to verify system performance and test patient cables. For user convenience, this function is built in to the BioZDx device.

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

Table 1 Device Equivalency

Attribute	BioZDx (New)	BioZ.pc (Predicate)	BioZ.com (Predicate)
Packaging	Separate computer and Patient Interface Module (PIM)	Separate computer and Patient Interface Module (PIM)	Self-contained instrument (computer and Patient Interface Electronics)
Pt. Interface Circuitry and sensors	Same as BioZ.com and BioZ.pc with addition of continuous lead fail. All accessories except patient cable same as BioZ.com	Same as new device with exception of continuous lead fail. All accessories except patient cable same as new device	Same as new device with exception of continuous lead fail. All accessories except patient cable same as new device
Defib Protection	Moved to yoke of patient cable	Internal to BioZ.pc Instrument	Internal to BioZ.com Instrument
CPU	Intel 586 equivalent PC	Intel 586 or Equivalent PC	Intel 386EX PC
CPU Packaging	Separate from patient interface circuitry, connected with serial link	Separate from patient interface circuitry, connected with serial link	Internal to BioZ.com Instrument
CPU Communications	USB Serial	RS323 Serial (External)	RS232 Serial (Internal)
PC Operating System	Windows CE®	Windows 98 or NT®	DOS 6.22
PC Software Installation Kit	Manufactured and supplied per CDIC Manufacturing Procedure 02-121	Manufactured and supplied per CDIC Manufacturing Procedure 02-121	Manufactured and supplied per CDIC Manufacturing Procedure 02-121
Printer	Internal to Cardiograph HPGL Protocol	Externally connected HPGL Protocol	Externally connected HPGL Protocol
User Interface software	BioZDx ver V1.0x9	BioZ.pc V1.52	BioZ.com V2.26
User Display	Internal VGA Screen	External PC VGA Screen	BioZ.com internal ¼ VGA screen
Blood Pressure Electronics	Internal to BioZ.dx PIM Suntech Module	Internal to BioZ.pc PIM Suntech Module	Internal to instrument CAS or Suntech Module
Pulse Oximeter Electronics	Discontinued as a product feature	Internal to PIM	Externally connected to instrument via serial data cable
DSP Packaging	Internal to PIM	Internal to PIM	Internal to BioZ.com Instrument
DSP Firmware	CDIC ZMARC+ Ver V00.04.16.10.09	CDIC ZMARC Ver1.09	CDIC ZMARC Ver 2.15
Patient Simulator	Built-In for user convenience	Separate Device (BZ-4525)	Separate Device (BZ-4525)

Risk Analysis and Design Controls

A Risk Analysis assessment, performed on the BioZDx, revealed that the repartitioning of the circuitry present absolutely no additional safety risks. The System Hazard Analysis is included in Section J. The software Hazard Analysis is included in Section M.

CardioDynamics International Corporation is certified to EN13485, and audited by TUV Rhineland. No significant audit findings have been presented since EN14001 certification in May of 1998. All products designed and manufactured under CDIC's Quality System, which includes Design Control and Manufacturing Practices.

QSP-107 defines the following activities and deliverables related to all design activities:

- Design Input: Specific requirements for a design project, including any applicable statutory and regulatory requirements.
- Design Output: The results of a design effort. The design output includes 1) the detailed documentation covering all functional and performance characteristics of the device, including those related to safety, 2) the product and process documents needed to produce the device and maintain it throughout its life cycle.
- Design Verification: Confirmation that the design output meets the design input requirements.
- Design Validation: The establishment, by objective evidence, that a device conforms to the users' needs and intended uses.
- Design Transfer: The process of transferring knowledge (specifications) about the device from the design group to the manufacturing group.

It is the responsibility of all members of the Engineering Department to ensure that the requirements of QSP-107 are met for all product designs and that each required deliverable is created and approved.

It is the responsibility of the representatives of the Marketing, Quality Assurance, Manufacturing and Executive departments to review, understand and approve each applicable deliverable of the Design Control process.

The result of following QSP-107 is a Device Design Record that includes design documentation associated with the design of the product. The completed Device Design Record provides a design history of the finished device and demonstrates the device design was developed, verified and validated in accordance to QSP-107. The accessories developed specifically as part of the BioZDx Hemodynamic Monitor are included in its Device Design Record.

Design Review is required, at a minimum, at the completion of each step in the design control process (i.e. Design Input, Design Output, Design Verification, Design Validation and Design Transfer). The design review process identifies the required deliverables for each step in the process and verifies the content and accuracy of each deliverable. The Design Control Form, QSDP-101-1, contains a list of the deliverables for each step, with the approved revision number. The signatures on both the Design Control Form and each of the approved documents constitute evidence of the design review process.

Design inputs provide the foundation for product development. All Design Inputs are as comprehensive and precise as possible without imposing design solutions. Upon completion of the design review activity

for the Design Input step, with agreement that the Design Inputs were correct and acceptable, the Design Input section of the Design Control Form is completed with all required signatures.

The Design Output deliverables are to be created by appropriate personnel to meet the specific Design Input requirements. The Design Output deliverables demonstrate that the Design Input requirements have been met. These deliverables are listed in the Design Output section of the Design Control Form. Upon the completion of the design review activity for the Design Output step, with agreement that the listed Design Output deliverables were determined to be correct and acceptable, the Design Output section of the Design Control Form is completed with all required signatures.

Design Verification is performed by the appropriate personnel to verify the Design Outputs fulfill the Design Input requirements. The Design Verification deliverables indicate that the Design Outputs meet the specified Design Input requirements listed in the Design Verification section of the Design Control Form.

Design Validation is performed by the appropriate personnel to verify that the Design Outputs fulfills the users' needs and intended uses. The Design Validation documents indicate the Design Outputs meet the users' needs and intended uses, and are listed in the Design Validation section of the Design Control Form. Upon the completion of the design review activity for the Design Validation step, with agreement that the listed Design Validation deliverables are determined to be correct and acceptable, the Design Validation section of the Design Control Form is completed with all required signatures.

Design Transfer activity is performed by appropriate personnel to verify that the Design Output and Design Transfer deliverables are sufficient to produce a product that meets the Design Input requirements. The Design Transfer deliverables include manufacturing instruction and documentation, in addition to the Design Output deliverables that are sufficient to produce a device that meets the Design Input requirements and shall be listed in the Design Transfer section of the Design Control Form. Upon completion of the design review activity for the Design Transfer step, with agreement that the listed Design Transfer deliverables are determined to be correct and acceptable, the Design Transfer section of the Design Control Form is completed with all required signatures.

The design process can be considered complete when all sections of each Design Control Form created during the project are signed. Upon completion of the design process, all design output documents are submitted for Document Change Order (DCO).

Configuration Control and Quality Assurance are provided under CDIC Quality System Procedures. These procedures specify that all products must be DCO control, that all components used in product assembly have incoming inspection, and that all product is built only under controlled manufacturing documentation, manufacturing instruction and test procedures. Internal audits are performed to insure compliance with these procedures.

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Cardiodynamics International Corp.
c/o Mr. Dennis G. Hepp
Chief Technology Officer
6175 Nancy Ridge Drive, #300
San Diego CA 92121

Re: K041294
    Trade Name: BioZDx Hemodynamic Monitor
    Regulation Number: 21 CFR 870.2770
    Regulation Name: Impedance Plethysmograph
    Regulatory Class: II (two)
    Product Code: DSB
    Dated: May 13, 2004
    Received: May 14, 2004

Dear Mr. Hepp:

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

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):_K041294

Device Name:_ BioZDx HemoDynamic Monitor

Indications For Use:

The BioZDx Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

ECG	Pre-Ejection Period	Systolic Time Ratio
Cardiac Output	Heart Rate	End diastolic Index
Thoracic Fluid Content	Acceleration Index	Cardiac Index
Left Vent. Ejection Time	Index of Contractility	
End Diastolic Volume	Mean Blood Pressure	Stroke Volume
Systemic Vascular Resistance		Systolic Blood
PressureLeft Cardiac Work		
Diastolic Blood Pressure		

Prescription Use _XXX___   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 Cardiovascular Devices
510(k) Number_K041294____