K051228/S1
p1/3

JUN 10 2005

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 BioZDx Hemodynamic Monitor
Model	5100
Manufacturer:	CardioDynamics International Corporation (CDIC)
Predicate Device 510(k):	K041294 on 12/6/04
Predicate device 2:	Philips PageWriter Trim Cardiograph
Model:	PageWriter Trim III
Manufacturer:	Philips Medical Systems (Philips)
Predicate Device 510(k):	K031422 on 7/3/03

Reason for Submission: The new product is the combination of two individually 510(k) cleared devices onto a single device platform. Both predicate devices presently use the identical common platform (CPU, display, printer, operating system) in their separate forms. The submission covers the changes necessary to the two predicate devices to allow co-residency of the Philips ECG PIM and its application software and the CardioDynamics ICG PIM and its application software into a single device. The new product combines the ECG functionality of the existing Philips PageWriter Trim III Cardiograph and the ICG functionality of the existing BioZDx monitor and allows switching between ECG and ICG applications. The ECG PIM is identical to PageWriter Trim Product including Philips' original product labeling and manuals. The PageWriter Trim application was modified by Philips to add an "Exit to ICG" function button and a common HIPPA-compliant timeout screen and password compatible with the existing CardioDynamics ICG application. The CardioDynamics application was modified to have an "Exit to ECG" button, and a "home" screen which allows initial selection of one of the two applications.

The BioZDx Hemodynamic Monitor and Philips 12-lead ECG is substantially equivalent and essentially identical to its predicate devices, the BioZDx currently marketed by CardioDynamics International Corporation (CDIC) and the Philips PageWriter Trim III Cardiograph currently marketed by Philips Medical System. The justification for this substantial equivalence determination is presented below.

The BioZDx Hemodynamic Monitor and Philips 12-lead ECG is substantially equivalent and essentially identical to the ICG function of the predicate BioZDx in terms of design, intended use and principles of operation. The ECG function of the BioZDx Hemodynamic Monitor and Philips 12-

lead ECG is substantially equivalent and essentially identical to the predicate Philips PageWriter Trim III in its design, intended use, and principles of operation. The electronics package and platform (CPU, display, printer, and operating system) of the CDIC predicate device has always been that of the Philips PageWriter Trim III product with the ECG PIM and the application software removed. The new product contains the individual application software of both products with the addition of a home screen to select the application of choice on power-up, and the addition of an exit key to each applications to switch between functions. These new functions are described in Section I-4 "DDR-071-10 BioZ Dx Combo Product CardioDynamics User Software Requirements Specification"

The Philips PageWriter Trim III application was further modified to add a HIPPA-compliant timeout screen that shares a common password with the ICG application. The BioZDx predicate device already had the HIPPA-compliant timeout and password functions. Modifications to the PageWriter Trim III application software were completed and tested by the Philips PageWriter Trim III design team in China. The changes to the Philips PageWriter Trim III application are described in Section I-3, "CDIC BioZ Combo Product ECG Software Design Specification". Test reports are included in Section J that verify the new functionality and demonstrate compatibility of the two applications and two PIM's co-residing on the platform. All testing (both at CardioDynamics and Philips) was performed with both PIMs attached. The product design, along with the Windows CE operating system, only permits one of the two applications to be running at any given time.

A small modification was made to the ICG DSP firmware to simplify the operation of the signal status indicator for the user. A verification report of this change is attached in Section J.

The Application Software which provides the user interface for the separate ECG and ICG applications of the BioZDx System and Philips 12-lead ECG is loaded onto the platform using a software installation kit, identical to the method used for each of the predicate devices.

The user manual for the new product (included in Section H) was modified to include the existence of the ECG functionality and references the Philips product documentation that is provided with the system. Specific instructions are provided in the CDIC manual to contact CDIC rather than Philips for product support. The only other label change from either predicate device is the addition of a "Philips 12-lead" label to the enclosure (included in Section H).

There are no hardware changes from the predicate devices except the small "Philips 12-lead" label mentioned in the previous paragraph.

All accessories for the BioZDx and Philips 12-Lead ECG product are identical to those presently being marketed with the predicate devices.

All software changes to the new product from the predicate devices are verified and validated within the body of system and software testing. Product testing focused on verifying the small number of changes to the code in each application, and that the addition of the alternate application to the system did not affect the functionality of either application. The validation reports from CardioDynamics and Philips are included in Section J.

The ICG electrodes (BioZTect Sensor) to be used with the BioZDx device are sold separately, and are identical to those marketed for use with the BioZDx predicate device. The BioZTect Sensor received 510(k) Clearance (K001100) on 5-5-2000. The sample pack of ECG sensors shipped with the BioZDx Hemodynamic Monitor and Philips 12-Lead ECG (Vermed A10023) received 510(k) Clearance K030073.

The Device Master Record for the BioZDx Hemodynamic Monitor and Philips 12-Lead ECG product is held at CardioDynamics, where the product is manufactured using components manufactured by Philips and CardioDynamics. The ECG software is developed and maintained by Philips in China,

and released on a controlled basis to CardioDynamics where the executable application is stored and loaded using procedures within the CardioDynamics Quality System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2005

CardioDynamics International Corporation
c/o Mr. Dennis G. Hepp
Chief Technology Officer
6175 Nancy Ridge Drive, Suite 300
San Diego, CA 92121

Re: K051228
Trade Name: BioZDx Hemodynamic Monitor and Phillips 12-lead ECG, Model 5200
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II (two)
Product Code: DSB
Dated: June 02, 2005
Received: June 03, 2005

Dear Mr. Hepp:

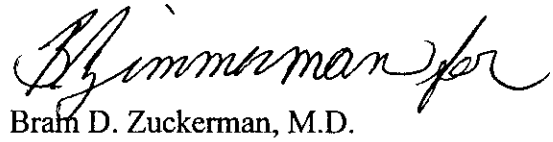
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0295. 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,



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

Enclosure

K051228/s

Indications for Use

510(k) Number (if known): K051228

Device Name: BioZDx HemoDynamic Monitor and 12-lead ECG

Indications For Use:

For the ICG function (from K041294):

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 Pressure**
Left Cardiac Work	**Diastolic Blood Pressure**	

For the optional 12-lead ECG function (from K031422):

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

Prescription Use _XXX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K051228