

SECTION 2 -- SUMMARY AND CERTIFICATION**A. 510(K) SUMMARY****SUBSTANTIAL EQUIVALENCE:**

Identification of predicate device, model and manufacturer:

Predicate device: CardioDynamics BioZ Portable System

Model: BZ - 125

Manufacturer: CardioDynamics International, Corp.

Predicate device 510(k) # K972320

Reason For Submission: Device Modification -- Repackaging

The BioZ.com System is substantially equivalent to its predicate device, the CardioDynamics BioZ Portable System currently being marketed by CardioDynamics International Corp. The justification for this substantial equivalence determination is presented below.

The BioZ.com System is substantially equivalent to the CardioDynamics BioZ Portable System in terms of design, intended use and principals of operation. Both systems are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of each systems is to noninvasively measure a patients hemodynamic parameters using thoracic electrical bioimpedance (TEB). Monitoring is accomplished by attaching 8 electrodes to the patient (two on each side of the neck and thorax) and injecting a minimal current through the upper electrodes and reading the returning voltage waveform from the inner electrodes.

Since both systems use the same CardioDynamics proprietary DSP circuitry and software, the formulas and algorithms used to calculate the various hemodynamic parameters are essentially the same. In addition, all required input parameters are the same, including patient gender, body frame size, height, weight, age and blood pressure.

The BioZ Portable System and the BioZ.com System are self-contained computer-based products utilizing the same CardioDynamics proprietary DSP circuitry and software. Each system consists of the following components:

1. Instrument:
 - A. CardioDynamics proprietary DSP and Patient Interface Circuitry
 - B. Intel 80X86 Processor Board
 - C. CardioDynamics proprietary DSP firmware and user software
 - D. Condor Medical grade power supply
 - E. Built in flat-panel screen
 - F. Keyboard/keypad
 - G. Power Cord
2. Patient Cable
3. Electrodes/Transducers

The key differences between the two devices are that the CardioDynamics BioZ Portable is based on an off-the-shelf (Dolch brand) PC based system utilizing a full QWERTY keyboard, while the BioZ.com is a CDIC-proprietary platform with built-in keypad and screen (a QWERTY keyboard is an optional accessory). In addition, the BioZ Portable operates exclusively on AC power while the BioZ.com can operate from AC power or from an internal rechargeable battery for limited patient transport use. Although the CardioDynamics proprietary DSP circuitry used in both devices is the same, partitioning changes were made to the boards used in the BioZ.com to accommodate the plastic enclosure and different Intel 80X86 family processor chip. The BioZ.com also provides a user-selectable option of a secondary equation for the calculation of the Stroke Volume parameter (Bernstein) in addition to the single Sramek-Bernstein equation in the BioZ portable.

Screen differences were required to accommodate the 320 x 240 dot display of the BioZ.com rather than the 640 x 480 dot display in the BioZ Portable. Screen differences between the BioZ Portable and the BioZ.com include:

1. While the BioZ System offered the Patient Data Entry, Monitoring, Indexed Data, Therapeutic, Indexed Therapeutic, Diagnostic, Interactive Trending and Trending Screens, the BioZ.com System will offer only the Patient Data Entry, Monitoring, Therapeutic, Diagnostic and Trending Screens. User configuration of the Monitoring, Diagnostic, and Trending screen in the BioZ.com makes the additional screens unnecessary.
2. On many of the BioZ Portable Screens, 7 to 10 parameters were shown at any given time. The BioZ.com System will display up to 5 parameters at a time.
3. The parameters shown on the individual BioZ Portable screens were pre-set and could not be changed. The BioZ.com System Monitoring, Diagnostic and Trending Screens can be configured to display a set number of the following parameters:

ECG	Heart Rate
Pre-ejection Period	Left Ventricular Ejection Time
Systolic Time Ratio	Stroke Volume
Cardiac Output	Cardiac Index
End Diastolic Volume	Systemic Vascular Resistance
Left Cardiac Work	Systemic Vascular Resistance indexed
End Diastolic Index	Index of Contractility
Acceleration Index	Left Cardiac Work Index
Thoracic Fluid Content	Respiration Rate

4. The Monitoring Screen in the BioZ.com can be configured to display any two of the following waveforms: Impedance, ECG, ΔZ , dZ/dT , Pacer Impulse, Spike Enhanced ECG and/or no waveform. The BioZ Portable always showed ECG, with a user option for a second waveform of either ΔZ or dZ/dT .

6. The Waveform Screen is new to the BioZ.com. The screen will show the five parameters selected by the user for the Monitoring Screen along with larger and longer displays of two of the waveforms available in the Monitoring Screen.
7. In the BioZ.com System software, there are a number of default values such as CVP, PAOP, height and weight units, automatic data save timing, etc. The user will be able to change the default values within the BioZ.com Software. The BioZ Portable had limited user control over default values.

Another difference between the BioZ Portable and the BioZ.com System is that the BioZ Portable was able to receive external data from two blood pressure devices and one pulse oximeter. The BioZ.com System will be able to receive and transmit data to many common hospital monitoring systems, using their established, documented protocols.

To demonstrate that the two systems are functionally equivalent, an Accuracy and Equivalency Test was performed comparing the CardioDynamics BioZ.com System to the CardioDynamics BioZ Portable. The purpose of the protocol was to demonstrate that the BioZ.com System is substantially equivalent to the CardioDynamics BioZ Portable System. Digitized waveforms from a number of patients with various clinical conditions were input into the BioZ Portable System and then the BioZ.com System. After one minute, three parameters were recorded for each device. The measurement and calculations performed by the device achieved the expected results.



MAR 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K974725
BIOZ.COM SYSTEM
Regulatory Class: II (two)
Product Code: 74 DSB
Dated: December 18, 1997
Received: December 23, 1997

Dear Mr. Hepp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **BioZ.com Hemodynamic Monitor**

Indications for Use:

The BioZ.com Hemodynamic Monitor is intended to monitor a patient's hemodynamic parameters. These parameters include:

- | | |
|-------------------------------------|---------------------------------------|
| ECG | Heart Rate |
| Pre-ejection Period | Left Ventricular Ejection Time |
| Systolic Time Ratio | Stroke Volume |
| Cardiac Output | Cardiac Index |
| Systemic Vascular Resistance | End Diastolic Volume |
| End Diastolic Index | Index of Contractility |
| Acceleration Index | Left Cardiac Work |
| Thoracic Fluid Content | Respiration Rate |

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices
 510(k) Number _____

Prescription Use
 (PER 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)