K021517
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510 (k) Summary

Submitter:

Mark Rosoff, President
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Contact: Mark Rosoff
Date of Summary: 05-10-02

Name of Device: ABP for Windows
Common Name: RZ250 Ambulatory Blood Pressure Software
Classification Name: Blood Pressure Computer (as per 21 CFR 870.1110)

Substantial Equivalence claimed to legally marketed device:
Mobile-O-Graph Blood Pressure Monitor , Model ABP Control- K964235

Description of Device:

The ABP for Windows Software is a software designed to be used in conjunction with I.E.M's Mobile-O-Graph Blood Pressure Monitor, Model ABP Control (K964235). The software will allow the user to program the Mobile-O-Graph using the software by inputting patient identification, protocols and setting recorder clock. The software will have the ability to download the data recorded from the Mobile-O-Graph to the computer to be reviewed by a trained professional. The software will allow the data to be printed and e-mailed in PDF or HTML format if desired. The ABP for Windows does not perform any diagnosis or provide any interpretation of data, it can only display and print the downloaded data such as systolic, diastolic, heart rates and mean arterial blood pressure in tabular or graphical form which was recorded by the Mobile-O-Graph. The physician will be able to review, edit and print the data collected. The ABP for Windows will provide information such as when patient events occurred , errors during recording and when day and night were marked on the Mobile-O-Graph. The software ABP for windows will be shown to be substantially equivalent to the software which is provided by I.E.M.'s Mobile-O-Graph Blood Pressure Monitor, Model ABP Control.

Intended use of Device:

The ABP for Windows software is designed to allow the user to program the Mobile-O-Graph via the computer and to download the data recorded on the Mobile-O-Graph after a 24 or 48 hour period. The software will store and playback systolic, diastolic, and heart rates recorded to be reviewed by a trained physician or other health care providers.

Comparison of Technology characteristics compared to predicate device:

Specifications	Predicate Device Mobile-O-Graph Blood Pressure Monitor ABP Control	New Device ABP for Windows
Type	IBM PC XT compatible	IBM PC XT compatible
CPU	40 MHz or greater	550 MHz Pentium or greater
RAM	8 Mbytes minimum	64 Mbytes minimum
Hard disk	2 Mbytes minimum	2 Mbytes minimum
Display	VGA	SVGA
Hard Disc Drive	1.4 Mbytes	1.4 Mbytes
Operating System	Windows 3.1	Windows 98 or greater
Port	One free serial port	One free serial port
Printer	Printer as any Windows compatible	Printer as any Windows compatible

Conclusion:

The ABP for Windows and the Mobile-O-Graph Blood Pressure Monitor, ABP Control Software are both used in clinical applications to allow trained physicians or other health care providers to program, download, review and print data from the Mobile-O-Graph Blood Pressure monitor. Both are computerized programs which display a pre-digitized patient image file run under a computer operating system. Both use the computer operating system to access the displayed image. The ABP for Windows conforms to Good Manufacturing Procedures outlined by the FDA cGMP. This software is safe and effective for the application for which it is intended and has been tested to confirm the safety and efficacy of the software. The APB for Windows is found to be **substantially equivalent** to the Mobile-O-Graph Blood Pressure Monitor, ABP Control Software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2002

Rozinn Electronics, Inc.
c/o Mr. Mark Rosoff
President
71-22 Myrtle Avenue
Glendale, NY 11385-7254

Re: K021517
Trade Name: ABP for Windows
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II (two)
Product Code: DSK
Dated: May 10, 2002
Received: May 10, 2002

Dear Mr. Rosoff:

This letter corrects our substantially equivalent letter of July 24, 2002, regarding the trade name.

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.

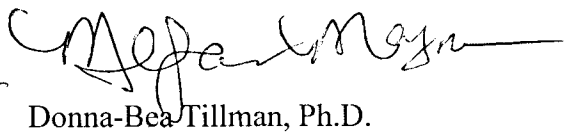
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Revised 7-30-2002

510(K) Number (if known): ___K021517_____

Device Name: ABP for Windows

Indications for Use:

The APB for Windows is a software package to be used by a trained physician or health care provider to load, download, review and print data from the Mobile-O-Graph blood pressure monitor. The software will store and playback systolic, diastolic pressures as well as patients heart rates to be reviewed by a trained physician.

Division of Cardiovascular & Respiratory Devices
510(k) Number K021517