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APR - 5 2002

510 (k) Summary

Submitter:

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Contact: Mark Rosoff
Date of Summary: 11-07-01

Name of Device: Netlink/Netscan
Common Name: ECG Transmission System
Classification Name: Transmitters and receivers, Electrocardiograph telephone (per 21 CFR 870.2920)

Substantial Equivalence claimed to legally marketed device:
PaceArt HomeTrak Plus EASI Event Recorder System- 510(k) K982090

Description of Device:
Netlink/Netscan is an accessory to Northeast Monitoring's Holter for Windows Holter Scanner (K930564) that sends recorded cardiac ECG data from remote sites to a central site using standard TCP/IP transfer protocols and where the central site is equipped with Northeast Monitoring's Holter for Windows Holter Scanner for analysis. Northeast Monitoring's Holter for Windows Holter Scanner software analyzes the ECG and provides reports on a variety of cardiac data. The cardiac data which is analyzed are individual ECG waveforms and patterns of consecutive waveforms. The analysis is then returned to the remote site and interpreted by trained medical personnel to diagnose patients with cardiac rhythm patterns.

Netlink/Netscan is an accessory that provides a means to transmit data to and from Northeast Monitoring's Holter for Windows Holter Scanning System . Data can be transferred via modem, cable modems, ISDN lines, T1 lines, DSL, Internet or Intranet. All transferred data is encrypted and is only accessed through a password controlled by the remote and central sites. Netlink/Netscan software contains data checks to prevent the loss or corruption of data during transmission. Nelink/Netscan will resend data if transmission is interrupted.

Intended use of Device:
This transmission software will transfer ECG, ambulatory blood pressure, EKG, spirometry and any other data files from a remote site to a central station for analysis using modem, cable modem, ISDN lines, T1 lines, DSL, Internet or Intranet for analysis and send the analyzed data back to the remote site from the central site using the same transmission media.

Comparison of Technology characteristics compared to predicate device:

Specifications	Predicate Device Paceart HomeTrak Plus EASI Event Recorder System	New Device Netlink/Netscan Central Site
Type	IBM PC AT Compatible	IBM PC AT Compatible
CPU	166 Mhz Pentium or greater	550MHz Pentium or greater
RAM	2 Mbytes Minimum	2 Mbytes Minimum
Hard disk	2.1 Gbytes Minimum	2.1 Gbytes Minimum
Display	SVGA	SVGA
Modem	28.8K with dedicated line	Yes
Cable Modem	No	Yes
Internet	No	Yes
ISDN Line	No	Yes
T1 Line	No	Yes
DSL	No	Yes

Specifications	Predicate Device Paceart HomeTrak Plus EASI Event Recorder System	New Device Netlink/Netscan Remote Site
Type	IBM PC AT Compatible	IBM PC AT Compatible
CPU	166 Mhz Pentium or greater	550 MHz Pentium or greater
RAM	32 Mbytes Minimum	256 Mbytes Minimum
Hard disk	2.1 Gbytes Minimum	2.1 Gbytes Minimum
Display	SVGA	SVGA
Modem	28.8K with dedicated line	Yes
Modem Cable	No	Yes
Internet	No	Yes
ISDN Line	No	Yes
T1 Line	No	Yes
DSL	No	Yes
Network Card	No	Yes

Conclusion:

The only difference between the Netlink/Netscan and the Paceart HomeTrak Plus EASI Event Recorder System is the use of transmission systems used. The Netlink/Netscan will transmit data using Internet, ISDN Lines, DSL, T1 Lines, Cable Modem and Modem whereas the PaceArt HomeTrak Plus EASI Event Recorder System only transmits data using a modem. In summary the performance between the two systems were nearly identical and supports the claim that they are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2002

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

Re: K020213
Trade Name: Netlink/Netscan
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: January 11, 2002
Received: January 22, 2002

Dear Mr. Rosoff:

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,

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

Enclosure

K020213

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K020213

Device Name: Netlink/Netscan

Indications for Use:

The Netlink/Netscan is a transmission software which will transmit ECG, ambulatory blood pressure, EKG, spirometry, and any other data files from a remote site to a central station for analysis using a modem, cable modem, ISDN line, T1 lines, DSL, Internet or Intranet and send the analyzed data back to the remote site from the central site using the same transmission media.

Division of Cardiovascular Devices
510(k) Number K020213

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