2/19/99

K982034

Section 2
Summary

The following is a Summary of the E-FAX System with Pacemaker Follow-Up Services substantial equivalence and safety and efficacy.

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Submission Correspondent:
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071-3404
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CLASSIFICATION NAME	Transmits and receives Electrocardiograph, Pacemaker Follow-up, Telephone.
COMMON/USUAL NAME	ECG Transtelephonic Transmitter and Receiver
PROPRIETARY NAME	E-FAX System with Pacemaker Follow-up
CLASSIFICATION	The agency has not established classification for this device. This device has been designated as a Class II device. The Panel is Cardiovascular 74DXH.
PERFORMANCE STANDARDS	None established under Section 514 of the Act.
PREDICATED DEVICE	Paceart System CardioVoice System K880283, K931296 and K952065,
INDICATIONS	The E-FAX Pacemaker Services software is designed to provide an additional program directory in the E-FAX System to support scheduling, receiving, and annotating transtelephonic pacemaker magnet testing and ECG strips using a pacemaker telephonic transmitter provided to the patient by his/her physician. The E-FAX System is released to market via section 510 (k) of the Act document # K932859.
DEVICE DESCRIPTION	The E-FAX Pacemaker Services software is an **add on** to the present E-FAX System software (K932859), that provides additional program directory in the E-FAX System to support scheduling, receiving, and annotating

	transtelephonic pacemaker magnet testing using a pacemaker transmitter provided to the patient by his/her physician.
PERFORMANCE TESTING Non-Clinical tests Clinical (parallel reviews)	Non-clinical tests provided included system acceptance testing and software validation. E-FAX recordings were taken from 53 volunteers using the E-FAX System with Pacemaker Services software and transmitting the electrocardiograms over telephone lines in parallel with released devices. The quality of the electrocardiograms in very case is equivalent.
CONCLUSIONS	The E-FAX Pacemaker Services software is equivalent in safety and efficacy to its predicated device.

Comparison to predicated device.

Parameter	E-FAX system with Pacemaker Services	Paceart Systems
Hardware and Software System	Yes	Yes
Automatic recording of ECG	Yes	Yes
Printer or fax print out of ECG	Yes	Yes
Record of Pacemaker model and type.	Yes	Yes
Record of Magnet tests	Yes	Yes
Uses "POT" phone line	Yes	Yes
System records contain complete patient data.	No, pacemaker follow-up only.	Yes
Can schedule follow-up appointments.	Yes	Yes
Can be setup to dial pager.	Yes	Yes
Can use any analog FM patient transmitter.	Yes	Some
Transtelephonic ECG Sampling Rate	200 Hz	150 Hz
Dedicated IBM compatible PC receiver	Yes OS2 O/S	Yes Win95 or NT O/S
Patient data base limited only by computer system	Yes	Yes
System records data only without modification or interpretation	Yes	Yes

modifies displayed results		
Electronic calipers for measurement of rate and interval	Yes	Yes
K #	K932859 E-FAX System K883152 Electronic calipers	Parts of K880283, K931296 and K952065

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Mr. J. Harvey Knauss
Consultant
Blakbag Limited
Division of Coherent Systems
c/o Delphi Consultant Group
11874 South Evelyn Circle
Houston, TX 77071-3404

Re: K982034
E-FAX System
Regulatory Class: II (two)
Product Code: DXH
Dated: January 13, 1999
Received: January 19, 1999

Dear Mr. Knauss:

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 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). 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 (Premarket 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 premarket 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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 : K982034

Device Name: E-FAX System with Pacemaker Services

Indications for use: The E-FAX Pacemaker Services software is designed to provide an additional program directory in the E-FAX System to support scheduling, receiving, and annotating transtelephonic pacemaker magnet testing and ECG strips using a pacemaker telephonic transmitter provided to the patient by his/her physician.

Prescription Device. Federal Law (US) restricts this device to sale by or on the order of a physician.

(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, Respiratory,
and Neurological Devices
510(k) Number K982034

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)