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**510(k) Summary**  
**October, 1998**  
**K983626**  
Gary N. Mills

Trade name - King of Hearts Express® II  
King of Hearts Express® EZ II

Common name - ambulatory event recorder

Classification name - telephone electrocardiograph transmitter and receiver (per 21 CFR 870.2920)

These devices are intended for use by patients who need to record their ECG during daily activities for subsequent transmission to a clinic, service, or hospital. These patients may have been instructed by their physician to record their ECG for the purpose of documenting transient symptoms which may suggest cardiac arrhythmia. The telephonic use of these devices allows the patient to receive advice based on their ECG and symptoms in a timely manner.

These devices are non-invasive, external ambulatory electrocardiographic (ECG) memory monitors. They are designed for evaluation of transient symptoms like dizziness, palpitations, and chest discomfort, and may be incorporated as part of rehabilitation, or medical treatment follow-up, where such symptoms may be present.

Features and functions are identical to identified predicate devices which include the Instromedix King of Hearts Express® 3X, Prince, and 1200, the Instromedix CarryAll, the Braemar ER720, the TZ Medical HeartAide Plus II, and the Card Guard CG-6500.

The new devices are capable of recording one or more leads of surface ECG. The additional features options permit automatic recording of ECG based upon measured heart rate or changes in heart rate, and/or pacemaker pulse detection and enhancement. A serial port connection is available for data communication, in addition to the standard acoustically coupled FM signal provided for trans-telephonic communications of the ECG.

The safety and effectiveness of these devices is substantially equivalent to the predicate devices. There are no known contraindications for use of this type of device. The multi-lead ECG, pacemaker pulse enhancement, rate-triggered recording, and other features in one or both of these devices present a non-significant risk to the host. These devices are categorized as Class II, non-significant risk devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 5 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Alaris Medical Systems  
c/o Gary N. Mills  
7431 NW Evergreen Parkway  
Hillsboro, OR 97124

Re: K983626/S1  
Trade Name: King of Hearts Express® II and King of Hearts Express® EZ II  
Regulatory Class: II  
Product Code: 74 DXH  
Dated: January 14, 1999  
Received: January 19, 1999

Dear Mr. Mills:

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.

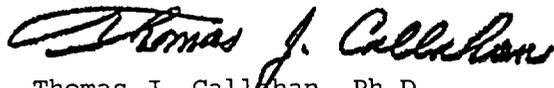
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): K983626

Device Name: King of Hearts Express® II

Indications For Use:

The King of Hearts Express® II cardiac event recorder is a patient-activated device designed for diagnostic evaluation of transient symptoms such as dizziness, palpitations, syncope and chest pain. The recorder provides single lead or multiple lead ECG morphology, which may be used to visualize arrhythmias, ST segment changes, SVT, heart block, re-entrant phenomena, and p-waves. The recorder may also provide automatic recording for detected bradycardia or tachycardia rhythms. The recorder may be used with pacemaker patients to assess pacemaker activity.

(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 K983626

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)