K052767

JUN 2 3 2006

SECTION 5: 510(k) Summary

Submitter:	Lechnologies Research, Inc.
Contact Person:	Tim Lohman, President
Date Prepared:	September 29, 2005
Trade Name:	The AfibAlert™ Atrial Fibrillation Detector
Classification:	Class II 21 CFR 870.2920 – Telephone electrocardiograph transmitter and receiver
Product Code:	DXH
Predicate Device(s):	The subject device is equivalent to the following devices: • The King of Hearts Express AF (K020825), manufactured by Instromedix • The CG-2211 SelfCheck ECG Transmitter (K012223), manufactured by Card Guard Scientific Survival Ltd. • The HeartCard (K010945), manufactured by Instromedix
Device Description:	The AfibAlert™ is a cardiac event recorder capable of storing five 45-second events in solid-state non-volatile memory. AfibAlert™ allows patients who have been diagnosed with, or are susceptible to developing atrial fibrillation (AF) to take periodic readings with a computerized rhythm monitor. The system was developed for the patient that has been previously diagnosed with AF, has a history of heart bypass, ablation, or other cardiac abnormality, or is on heart (anti-arrhythmic) medication. In these cases, detecting and determining AF early can potentially reduce the risk of heart attack and stroke. The device can record a single channel of ECG data in three ways: (1) via the two thumb electrodes, (2) by placement on the chest, or (3) by applying wrist electrodes. In each case, the patient initiates the recording. The recording takes approximately 45 seconds. Immediately following data acquisition, an internal AF algorithm is used to analyze the patient's rhythm. The appropriate LED (light emitting diode) is illuminated to indicate the presence or absence of AF. If AF is indicated, or concerning symptoms are present, the patient makes a telephone call to a service provider as specified by their physician and transmits the ECG data to the receiving personnel. Data can also be transferred by using a computer.
Intended Use:	The AfibAlert™ is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.
Functional and Safety Testing:	Electrical, mechanical, and software testing was conducted and data was collected in accordance with applicable standards to ensure that the device performs according to specifications and to verify that the device is suitable for home use.
Conclusion:	Lechnologies Research Inc. considers the AfibAlert™ Atrial Fibrillation Detector to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, method of use for self-monitoring, and indications for use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Lechnologies
c/o Ms. Stephanie King
Senior Regulatory Consultant
450 Olsen Memorial Highway
Minneapolis, MN 55422

Re: K052767
Trade Name: Afibalert Atrial Fibrillation Detector
Regulation Number: 21 CFR 870-2920
Regulation Name:Telephone electrocardiograph transmitter and receiver
Regulatory Class: II (two)
Product Code: DXH
Dated: May 25, 2006
Received: May 26, 2006

Dear Ms. King

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), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

K052767

Section 4: Indications for Use Statement

Device Name: AfibAlert™

The AfibAlert™ is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(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 Devices
510(k) Number K052767