K071228

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Sponsor:

Signalife, Inc.
531 S. Main St. #301
Greenville, SC 29601
Phone (864) 233-2300
Facsimile (864) 233-2100

NOV 2 1 2007

Contact Person: William R. Matthews, Regulatory Affairs

Date Prepared: April 30, 2007

2. Device Name: Signalife Fidelity 200 Cardiac Event Recorder

Trade or Proprietary Name:
Fidelity 200 Cardiac Event Recorder

Common or Usual Name:
Cardiac Event Recorder

Classification Name:

- 21 CFR 870.2920 – Transmitters and Receivers Electrocardiograph, Telephone
- 21 CFR 870.2800 – Medical Magnetic Tape Recorder

3. Predicate Devices:

The Signalife Fidelity 200 Cardiac Event Recorder is equivalent to:

- HeartCard® Telephone Electrocardiograh Transmitter and Receiver, K010945, Instromedix, Inc.
- Card Guard CG-2206 1-Lead ECG Event Recorder, K963725, Instromedix, Inc.
- CG-2211 Self Check ECG Transmitter, K012223, Card Guard Scientific Survival, LTD

4. Intended Use:

The Signalife Fidelity 200 Cardiac Event Recorder is a battery operated, single lead ECG event recorder capable of recording one, 45-second event of ECG data for the purpose of transtelephonic transmission to a cardiac monitoring station for analysis and diagnosis by a medical professional where cardiac monitoring is

desired by a subscriber to the service. The system includes recording of a single 45-second ECG and transtelephonic transmission of the recorded data to a monitoring station.

The ECG recording is then transferred to another device, such as the PaceArt® System K024278 manufactured by Medtronic, Inc. for ECG analysis. The Signalife Fidelity 200 Cardiac Event Recorder is not intended to sound any physiological alarms.

The Signalife Fidelity 200 Cardiac Event Recorder can be obtained over-the-counter (OTC) or direct-to-consumer by qualified individuals who wish to have access to a cardiac monitoring service.

5. Device Description:

The device acquires an ECG signal and produces a single lead ECG. Upon user activation, an ECG signal is acquired and digitized producing a 45-second ECG recording utilizing the company's signal processing technology.

The Signalife Fidelity 200 Cardiac Event Recorder converts the signal stream into a specific data format where it is stored on a memory chip for transtelephonic transmission to and analysis by another device such as the PaceArt System K024278 manufactured by Medtronic, Inc.

Recorded data is not real time but stored for further analysis. The Signalife Fidelity 200 Cardiac Event Recorder is not intended to evaluate the signal or alarm.

The fundamental technology of the Signalife Fidelity 200 Cardiac Event Recorder is the same as that of the predicate devices. The Signalife Fidelity 200 Cardiac Event Recorder employs the company's signal processing technology to minimize noise in the ECG signal created by the ambulatory nature of the signal source.

6. Basis for Substantial Equivalence:

The Signalife Fidelity 200 Cardiac Event Recorder and the referenced predicates all have substantially equivalent intended use, target population, technical characteristics, performance and compliance to consensus standards for the recording and transtelephonic transmission of ECG data for analysis.

An examination of the differences between the Signalife Fidelity 200 Cardiac Event Recorder and the predicate devices does not raise new questions of safety or effectiveness.

It is our determination that the Fidelity 200 is safe, effective and performs within its design specifications and is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Signalife, Inc.
c/o Mr. William Matthews
Regulatory Affairs
531 South Main St.
Greenville, SC 29601

Re: K071228
Trade/Device Name: Fidelity 200 Cardiac Event Recorder
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH, DSH
Dated: October 31, 2007
Received: November 1, 2007

Dear Mr. Matthews:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K071228

Device Name: Signalife Fidelity 200 Cardiac Event Recorder

Indications for Use:
The Signalife Fidelity 200 Cardiac Event Recorder is a battery operated; user-activated ECG event recorder and transmitter intended to record an ECG by patients who subscribe for the service. This allows users to record and transmit their ECG data to medical professionals via a communication device to a cardiac monitoring center. The Signalife Fidelity 200 Cardiac Event Recorder is intended for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal cardiac rhythms: Skipped beats, Pounding heart (Palpitations), Heart racing or irregular pulse, Lightheadedness or Faintness, History of Arrhythmia

Contraindications for Use:
In order to use this service, the patient must be able to perform all of the following: Read and understand the Instructions for Use, Place the Event Recorder on their chest and hold it steadily for at least 45 seconds, Hear the indicator beeps, Speak and understand English, Operate a telephone, Operate a simple, push button device. Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons who have been diagnosed with the following conditions should consult their physician before using this service: Blockage of the arteries of the heart, Heart valve problems, Heart transplant, Congestive heart failure, Loss of consciousness. If the user has any of these conditions, Signalife will need to obtain authorization from their physician before enrollment in the service.

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (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)

Mark Mays for DDE

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071228

Warning: *This device is not designed to be used with pacemakers or defibrillators. If the user has either of these, they will not be allowed to enroll in this service. The Signalife Fidelity 200 Cardiac Event Recorder cannot predict or diagnose a heart attack or be used for chest pain monitoring and is not a substitute for medical attention. This device is for monitoring purposes only and has no therapeutic value. It provides the individual access to cardiac monitoring services.*

Need for Signed Subscriber Agreement: Your agreement indicates you understand that Signalife (or affiliate) will contact your physician to verify in writing that you are their patient and that they are willing to be contacted in cases where there are clinically significant events involving your care. Your agreement indicates you understand that if written verification is not received from your physician within 35 days of your enrollment, you will not be able to utilize any aspects of the Signalife (or affiliate) service until such verification is received by Signalife (or affiliate). Your agreement certifies you understand that this service is not a substitute for physician care and that this is only a screening service.
Signalife, Inc Indications for Use Signalife Model 200 Cardiac Event Recorder