



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (lcs)
FOLDER: K122356 - 303 pages
COMPANY: ALIVECOR, INC. (ALIVECOR)
PRODUCT: ELECTROCARDIOGRAPH (DPS)
SUMMARY: Product: ALIVECOR HEART MONITOR FOR IPHONE

DATE REQUESTED: Oct 27, 2014

DATE PRINTED: Oct 27, 2014

Note: Printed





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

NOV 19 2012

Alivecor, Inc.
c/o Mr. Michael Righter
Director, Regulatory Affairs
140 Geary Street, Suite 500
San Francisco, CA 94108

Re: K122356
Trade/Device Name: Alivecor heart monitor for iphone
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: October 18, 2012
Received: October 20, 2012

Dear Mr. Righter:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Page 2 – Mr. Michael Righter

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Owen P. Faris -S

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

Enclosure



510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K122356

Device Names: AliveCor Heart Monitor for iPhone

Indications for Use:

The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use X

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

AND/OR

(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)

Owen P. Faris -S

2012.11.19

16:09:42 -05'00'



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

August 06, 2012

ALIVECOR, INC.
 SAN FRANCISCO
 140 GEARY STREET
 SUITE 500
 SAN FRANCISCO, CALIFORNIA 94108
 ATTN: MICHAEL RIGHTER

510k Number: K122356

Received: 8/3/2012

Product: ALIVECOR HEART MONITOR FOR IPH

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'mike@livecor.com'
Sent: Monday, August 06, 2012 8:13 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mike@livecor.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

K1223520
CVI ISCS



**510(k) PREMARKET NOTIFICATION
TRADITIONAL 510(k) COVER LETTER**

July 31st, 2012

FDA CDRH DMC

AUG 03 2012

Received *[Signature]*

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern;

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market and manufacture an ECG Event Recorder, known with the proprietary name of *AliveCor Heart Monitor for iPhone*.

The following information is being submitted in conformance with 21 CFR 807.92:

Submitter's Name: AliveCor, Inc.
Submitter's Address: 140 Geary Street, Suite 500, San Francisco, CA 94108
Facility Registration Number:
Contact Person: Michael S. Righter
Contact Person Title: Director, Regulatory Affairs
Telephone: 415.347.2212
Fax: 415.397.0440
Email: mike@alivecor.com
510(k) Submission Type: Traditional 510(k)
Date Prepared: July 31, 2012
Classification Name: Electrocardiograph
Common Name: ECG Event Recorder
Proprietary Name: AliveCor Heart Monitor for iPhone
Model Number: AC-001
Product Code: DPS
C.F.R. Section: 870.2340
Recommended Classification: Class II
Classification Panel: Cardiovascular
Reason for Submission: New Device



Confidentiality Statement, in accordance with 21 CFR 807.95

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA during the evaluation process, in accordance with (21 CFR 807.95).

Design and Use of the Device

The following table summarizes the principal factors about the design and use of the devices

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Michael S. Richter
Director, Regulatory Affairs

AliveCor, Inc.
140 Geary Street, Suite 500
San Francisco, CA 94103

email: mike@livecor.com
main: 415.347.2212
fax: 415.397.0440

David Albert, MD
Founder, Chief Scientific Officer

AliveCor, Inc. (Oklahoma)
800 Research Parkway, Suite 339
Oklahoma City, OK 73104



510(k) PREMARKET NOTIFICATION RISK ASSESSMENT

This section contains the following reports:

- 02SLRA – ECG for iPhone System Level Risk Assessment
- 02SLHA – ECG for iPhone System Level Hazard Analysis

Note:

AliveCor, Inc. considers Risk Management to be a continual process and each of the documents contained in this section to be 'living' documents. These documents will be updated upon future device/system verification and validation, product surveillance, and other activities as described in AliveCor's Quality Management System procedures.

The Risk Assessment and Hazard Analysis are two documents in the ECG for iPhone Risk Management File. Other analyses such as a supplier risk assessment or a full manufacturing process FMEA will be added once we have clearance to market the device and are able to commit resources to building a deeper risk strategy.

 AliveCor	AliveCor, Inc. CONFIDENTIAL	Document #: 02SLRA	Rev: A	Page: 1 of 6
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TITLE:	ECG for iPhone System Level Risk Assessment
LOCATION:	Document Control\Design Documentation\ECG for iPhone
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Reviewed and Approved By:	Role	Name	Signature	Date
	Product Development	Bruce Satchwell		
	Software Development	Kim Barnett		
	Quality Assurance	Stephen Mordue		
	Regulatory Affairs	Michael Righter		
	Manufacturing Operations	Bruce Satchwell		
	Sales and Marketing	David McCaman		
	Document Control	David Peeler		

Change History

Revision	Date	Description of Change	Author
A	July 18, 2012	Initial version	David Peeler

 AliveCor	AliveCor, Inc. CONFIDENTIAL	Document #: 02SLRA	Rev: A	Page: 2 of 6
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 AliveCor	AliveCor, Inc. CONFIDENTIAL	Document #: 02SLRA	Rev: A	Page: 3 of 6
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1. INTRODUCTION

Potential hazards for the *AliveCor ECG for iPhone* (device) have been identified and are summarized in this report. Please refer to 02SLHA – ECG for iPhone System Level Hazard Analysis for specific hazards and mitigations.

The nature of the device is quite passive. The device is indicated for use “by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.” When the device is activated, it simply records the patient ECG so that later a qualified physician can review the data for analysis. The device is not relied upon during a life-sustaining situation. The device itself does not analyze data or attempt to provide diagnosis support; it only records and displays ECG data.

2. SCOPE

This risk assessment covers the following components of the *AliveCor ECG for iPhone*:

- AliveCor ECG Case,
- AliveCor ECG App,
- iPhone with manufacturer’s software.

3. RISK ASSESSMENT METHOD

Risk estimation is used to rate the risk associated with each cause of every hazard identified. Risk is determined by assessing the severity of harm and the probability of the occurrence of harm. For each hazard, the foreseeable potential consequences (harm) that may result from the hazard are estimated. The severity and probability of harm is determined from the scales below.

Table 1: Severity Ratings

Level	Description	Severity Rating
Catastrophic	Results in patient death	5
Critical	Results in permanent impairment or life-threatening injury	4
Serious	Results in injury or impairment requiring professional medical intervention	3
Minor	Results in temporary injury or impairment not requiring professional medical intervention	2
Negligible	Inconvenience or temporary discomfort	1

Table 2: Probability Ratings

(b) (4)



4. RISK EVALUATION

(b) (4)



5. HAZARD ANALYSIS TABLE

(b) (4)



6. RISK ASSESSMENT DISCUSSION

(b) (4)





6.1. Greatest Risk Index Values

(b) (4)



6.2. Common Failure Mode/Effects

(b) (4)



6.3. Application of Standards for Mitigation

Testing and certification to the following standards is specified as mitigation in the Hazard Analysis (02SLHA):

- ISO 13485,
- IEC 60601-1,
- IEC 60601-1-2.

 AliveCor	AliveCor, Inc. CONFIDENTIAL	Document #: 02SLRA	Rev: A	Page: 6 of 6
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7. RISK ASSESSMENT CONCLUSION

(b) (4)



8. REFERENCES

- 02SLHA – ECG for iPhone System Level Hazard Analysis
- 02SLRS – ECG for iPhone System Level Requirements Specification
- IEC 60601-1 – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971 – Medical devices – Application of risk management to medical devices

	AliveCor, Inc. CONFIDENTIAL	Document #: 02SLHA	Rev: D	Page: 1 of 17
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TITLE:	ECG for iPhone System Level Hazard Analysis
LOCATION:	Document Control\Design Documentation\ECG for iPhone
AliveCor, Inc. CONFIDENTIAL	
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	Role	Name	Signature	Date
Reviewed and Approved By:	Product Development	Bruce Satchwell		
	Software Development	Kim Barnett		
	Quality Assurance	Stephen Mordue		
	Regulatory Affairs	Michael Righter		
	Manufacturing Operations	Bruce Satchwell		
	Document Control	David Peeler		

Change History

Revision	Date	Description of Change	Author
A	April 12, 2012	Initial version	David Peeler
B	April 17, 2012	Complete draft, ready for review	David Peeler
C	May 2, 2012	Changes from review meeting of 25 April, 2012	David Peeler
D	July 17, 2012	Updated for AliveCor template Added HF005 for ECG printouts Updated Risk Probability Acceptance First official release	David Peeler



510(k) PREMARKET NOTIFICATION

Biocompatibility Testing

This section contains the following reports:

1. ECG FOR IPHONE TESTING

- Cytotoxicity (MEM Elution)
 - Testing Center of Sanitation & Environment Technology Institute, Soochow University
- Irritation (Skin Irritation)
 - Testing Center of Sanitation & Environment Technology Institute, Soochow University
- Sensitization (Closed Patch)
 - Testing Center of Sanitation & Environment Technology Institute, Soochow University



AliveCor, Inc.

AliveCor ECG

Traditional 510(k) Submission

Electronic



510(k) PREMARKET NOTIFICATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ALVECOR INC 140 Geary Street San Francisco CA 94108 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1679	2. CONTACT NAME Michael Righter 2.1 E-MAIL ADDRESS mike@alvecor.com 2.2 TELEPHONE NUMBER (include Area code) 415-3472212 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 <u>Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?		

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

19-Jul-
2012



DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER AliveCor, Inc. / Michael Righter	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 07/31/2012
3. ADDRESS (Number, Street, State, and ZIP Code) 140 Geary Street, Suite 500 San Francisco, CA 94108	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 415.347.2212 (Fax) 415.397.0440

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
 (Attach extra pages as necessary)

Common Name: ECG Event Recorder

Classification Name: Electrocardiograph

Proprietary Name: AliveCor Heart Monitor for iPhone

Model: AC-001

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Michael S. Righter (Title) Director, Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 140 Geary Street, Suite 500 San Francisco, CA 94108	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 415.347.2212 (Fax) 415.697.0440
	15. DATE OF CERTIFICATION 07/31/2012

Instructions for Completion of Form FDA 3674**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.



**510(k) PREMARKET NOTIFICATION
TRADITIONAL 510(k) COVER LETTER**

July 31st, 2012

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern;

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market and manufacture an ECG Event Recorder, known with the proprietary name of *AliveCor Heart Monitor for iPhone*.

The following information is being submitted in conformance with 21 CFR 807.92:

Submitter's Name: AliveCor, Inc.
Submitter's Address: 140 Geary Street, Suite 500, San Francisco, CA 94108
Facility Registration Number:
Contact Person: Michael S. Righter
Contact Person Title: Director, Regulatory Affairs
Telephone: 415.347.2212
Fax: 415.397.0440
Email: mike@alivecor.com
510(k) Submission Type: Traditional 510(k)
Date Prepared: July 31, 2012
Classification Name: Electrocardiograph
Common Name: ECG Event Recorder
Proprietary Name: AliveCor Heart Monitor for iPhone
Model Number: AC-001
Product Code: DPS
C.F.R. Section: 870.2340
Recommended Classification: Class II
Classification Panel: Cardiovascular
Reason for Submission: New Device



Confidentiality Statement, in accordance with 21 CFR 807.95

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA during the evaluation process, in accordance with (21 CFR 807.95).

Design and Use of the Device

The following table summarizes the principal factors about the design and use of the devices

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
140 Geary Street, Suite 500
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.347.2212
fax: 415.397.0440

David Albert, MD
Founder, Chief Scientific Officer

AliveCor, Inc. (Oklahoma)
800 Research Parkway, Suite 339
Oklahoma City, OK 73104



**510(k) PREMARKET NOTIFICATION
MARKET INTRODUCTION EXPLANATION LETTER**

July 31st, 2012

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To the reviewer(s);

Prior to my arrival at AliveCor, Inc. (AliveCor), the company and its employees had excessive media exposure and a prominent stance as a consumer device developer. As with many start-up companies, AliveCor began the development of the “iPhone ECG” consumer device without a structured approach to design controls and without oversight by compliance personnel who can ensure adherence to applicable regulations. Upon recognition that AliveCor was actually developing a medical device (renamed *AliveCor Heart Monitor for iPhone*), we began structuring a quality system and a process driven approach to product development efforts.

Along with quality system implementation and design controls, we began an effort to clean-up promotional literature/labeling including YouTube videos that were produced prior to proper controls being in place. This is an ongoing effort as many of the videos were not posted by AliveCor staff. I recognize the risks associated with un-reviewed/un-controlled promotional literature; therefore, it is one of my top objectives during the review period for this submission to complete the clean-up effort.

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
140 Geary Street, Suite 500
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.347.2212
fax: 415.397.0440



510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor for iPhone

Indications for Use:

The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

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)



510(k) PREMARKET NOTIFICATION

510(k) STATEMENT

(as required by 21 CFR 807.93)

I certify that, in my capacity as Director, Regulatory Affairs of AliveCor, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of Certifier)

Michael S. Righter

(Typed Name)

July 31, 2012

(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank



**510(k) PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(k)]**

I certify that, in my capacity as Director, Regulatory Affairs of AliveCor, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Michael S. Righter
(Typed Name)

July 31, 2012
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].



**510(k) PREMARKET NOTIFICATION
CLASS III CERTIFICATION AND SUMMARY
(As Required by 21 CFR 807.94)**

(To be submitted when claiming equivalence to a Class III device)

This section **does not apply**.



510(k) PREMARKET NOTIFICATION
Financial Certification or Disclosure Statement
(As Required by 21 CFR 54)

This section **does not apply**.



510(k) PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY TO INDUSTRY STANDARDS

The following table is a list of the FDA recognized standards used to evaluate the *AliveCor ECG for iPhone* device.

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

A declaration of conformity is provided below for each of the standards in the table above.



Declaration of Conformance

IEC 60601-1 (2005)

The AliveCor ECG for iPhone is in compliance with IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. The AliveCor ECG for iPhone has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1.

IEC 60601-1-2 (2007)

The AliveCor ECG for iPhone is in compliance with IEC 60601-1-2: Medical Electrical Equipment – Part 1: General Requirements for Safety, Collateral Standard: Electromagnetic compatibility – Requirements and Tests. The AliveCor ECG for iPhone has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1-2.

ANSI/AAMI EC38 (2007)

The AliveCor ECG for iPhone is in compliance with ANSI/AAMI EC38: Ambulatory Electrocardiographs. The AliveCor ECG for iPhone has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for EC38.

ISO 10993-1 (2009)

The AliveCor ECG for iPhone is in compliance with ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. The AliveCor ECG for iPhone has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for ISO 10993-1.



AliveCor™

510(k) PREMARKET NOTIFICATION

THIRD PARTY LABORATORIES USED FOR TESTING CONFORMANCE TO STANDARDS

Biocompatibility:

(b) (6)

EMC, ESD, and Environmental Testing:

(b) (6)

Manufacturer:

Manufactured for AliveCor by IDT Technology Ltd.
9/F, Kaiser Estate, Phase I, 41 Man Yue Street,
Hung Hom, Kowloon, Hong Kong

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (2005)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number³ #5-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2: Med. Elec. Equip. - Gen. Req. for Safety; Electromagnetic Compatibility - Reqs. and Tests (2007)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number³ #5-54

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI EC38: Part 2-47: Particular req's for the safety, including essential perf., of ambulatory electrocardiographic systems (2007)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number³ #3-65

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

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If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number³ #2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: #G95-1: Use of International Standard ISO-10993, 'Biological ... Testing'

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5	Part 5: Tests for in vitro cytotoxicity	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Cytotoxicity tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10	Part 10: Tests for irritation and skin sensitization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Irritation and Sensitization tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL OTHER		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION
All other parts not applicable to the he AliveCor Heart Monitor for iPhone according to the standard

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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510(k) PREMARKET NOTIFICATION

EXECUTIVE SUMMARY

1. INTRODUCTION

AliveCor, Inc. (AliveCor) has developed and plans to market an ECG Event Recorder known with the proprietary name of *AliveCor Heart Monitor for iPhone*. This device has the same general operating characteristics and a similar intended use as the previously cleared HeartCheck Pen Handheld Heart Rhythm with GEMS Home device (aka. "HeartCheck Pen" or predicate device) manufactured for CardioComm Solutions, Inc. Differences in the technical characteristics between the two devices are minimal and are primarily in response to a need to simplify the user interface by utilizing a Smartphone in place of a PC for data upload. We believe that the *AliveCor Heart Monitor for iPhone* is substantially equivalent to the HeartCheck Pen Handheld Heart Rhythm with GEMS Home (K121009).

2. BACKGROUND

Our experience with traditional ECG event recorders is that they are simply too expensive and cumbersome for users to fully appreciate and utilize the clinical benefits of mobile diagnostic ECG systems. AliveCor believes that by reducing the cost of the hardware portion of the device and simplifying the user interface by integrating a commonly used mobile computing platform, we will be able to improve the access to care, improve workflow and access to data for physicians, and improve a sense of awareness of patient health, thereby facilitating preventive medicine.

Typically, the high price of portable ECG monitors requires re-usage by many patients, which incurs high handling costs (cleaning/sterilization, shipping, servicing, inventory management, etc.). In addition, the complexity of ECG monitors including the predicate device impacts patient compliance negatively, and requires more training time with a medical technician or clinician to learn how to use the device.

AliveCor has designed and intends to market our own medical device to satisfy the unmet need to truly improve patient compliance, address the high product cost and improve access to care. The units have a simplified user interface compared to the predicate device, a simplified electronics and mechanical design that is low enough cost to be purchased by individuals, while still supporting the basic and necessary features offered by the predicate device and other ECG monitors currently on the market.

3. INTENDED USE

The *AliveCor Heart Monitor for iPhone* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (e.g. physician, nurse, EMT) with the ability to perform an immediate assessment of a patient's ECG rhythm. Additionally, the simple user interface allows a patient to directly acquire a recording from their own body for transmission-to and assessment-by a medical professional.

4. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

The AliveCor Heart Monitor for iPhone has no known contraindications; however, the device is issued via prescription only, and should be used in accordance with the instructions as indicated in the User Manual and as directed by a physician.

Refer to Section 13: Proposed Labeling for additional warnings and precautions.



5. DEVICE DESCRIPTION

The AliveCor Heart Monitor for iPhone (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the computing power of a Smartphone while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the patient's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the AliveCor Heart Monitor for iPhone uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the AliveCor Heart Monitor for iPhone uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the AliveCor Heart Monitor for iPhone Case (Case), AliveCor Heart Monitor for iPhone App (App), and the Apple iPhone 4/4S (iPhone) using iOS 5.1 or later.

6. SUBSTANTIAL EQUIVALENCE

Legally marketed predicate device:

510(k) Number: K121009

Product: HeartCheck Pen Handheld Heart Rhythm with GEMS Home

Manufacturer: CardioComm Solutions, Inc.

The major differences between the currently marketed HeartCheck Pen and the AliveCor Heart Monitor for iPhone are summarized below and detailed in Section 12: Substantial Equivalence discussion.

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Indications for Use:</i>	The HeartCheck™ Pen Handheld with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor ECG for iPhone is intended for use by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.
<i>Standards:</i> Essential Performance AECG Safety General Safety EMC Safety	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2



Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Data Acquisition:</i> Frequency Response ECG channels Resolution Sample Rate	1 Hz – 40Hz Single Channel Unknown 250 Samples/Second	0.5 Hz – 40 Hz Single Channel 16 bit 300 Samples/Second
<i>Memory Capacity:</i>	20 recordings	Essentially unlimited due to real-time transmission to iPhone memory
<i>Device Classification:</i>	DPS: Electrocardiograph	DPS: Electrocardiograph
<i>Power Supply:</i> Battery Battery Life (typical)	2 AAA batteries Unknown	1 Lithium Manganese Dioxide Coin Cells 100 hours operational
<i>User Interface:</i> Primary Lead Data upload Software platform	Lead I, Left to Right Hand USB PC based software	Lead I, Left to Right Hand Ultrasonic transmission iPhone OS based software
<i>Physical Specs:</i> Dimensions, inches Weight	130 x 30 x 20 mm 110 grams	118 x 62 x 16.5 mm 40 grams
<i>Electrodes:</i> Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel
<i>Lead Wires:</i>	None	None
<i>Where used:</i>	Ambulatory outpatient use	Ambulatory outpatient use
<i>Prescribed:</i>	Over-the-Counter	Prescription Only
<i>Environmental:</i> Operating Temp Storage Temp	5 to 40 degrees C -20 to 55 degrees C	10 to 40 degrees C -20 to 60 degrees C

None of the above differences in specification affect the safety or efficacy of the AliveCor Heart Monitor for iPhone compared to the HeartCheck Pen system as discussed in Section 12: Substantial Equivalence Discussion.

In addition to Section 12: Substantial Equivalence Discussion, additional testing was performed to demonstrate the safety and efficacy of the device in Sections 16: Software, Section 17: Electromagnetic Compatibility and Electrical Safety and Section 18: Performance Testing – Bench. The results of performance, safety and bench testing suggest that the main functional characteristics of the HeartCheck Pen and AliveCor Heart Monitor for iPhone are comparable for key metrics, thus confirming their substantial equivalence.



7. COMPLIANCE TESTING

The AliveCor Heart Monitor for iPhone was evaluated for conformity to the following list of standards. The AliveCor Heart Monitor for iPhone demonstrated compliance with all applicable tests. Greater detail is discussed in Section 9: Declaration of Conformity, Industry Standards.

Safety and Compliance Standards and Guidelines:

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

8. CONCLUSION:

The *AliveCor Heart Monitor for iPhone* represents a logical modification to the technology of the predicate device. The changes intended to improve the device performance and clinical value as a cardiac diagnostic device. The clinical use of the device remains identical to the predicate device. AliveCor has concluded that the *AliveCor Heart Monitor for iPhone* is substantially equivalent to the predicate device and the differences between them do not adversely affect safety and effectiveness of the device.



510(k) PREMARKET NOTIFICATION

DEVICE DESCRIPTION



Figure 1: User Interface



Figure 2: *AliveCor Heart Monitor for iPhone Case*

1. BASIC DESCRIPTION:

The *AliveCor Heart Monitor for iPhone* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the computing power of a Smartphone while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the patient's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor for iPhone* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor for iPhone* uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the *AliveCor Heart Monitor for iPhone Case (Case)*, *AliveCor Heart Monitor for iPhone App (App)*, and the Apple iPhone 4/4S (iPhone) using iOS 5.1 or later.

2. INTENDED USE:

The *AliveCor Heart Monitor for iPhone* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (e.g. physician, nurse, EMT) with the ability to perform an immediate assessment of a patient's ECG rhythm. Additionally, the simple user interface allows a patient to directly acquire a recording from their own body for transmission-to and assessment-by a medical professional.

3. PATIENT BENEFITS:

Traditional ECG monitors that use telephone transmission techniques require the patient to record their ECG then at some later time, use a phone (typically a land-line) to transmit the data to a service center. The *AliveCor Heart Monitor for iPhone* simplifies the process for the patient by removing the need to manually transmit the data. The device automatically records the data on the smartphone and the associated smartphone application uploads the data with minimal patient interaction.

AliveCor, Inc. (AliveCor) believes that by removing the complexity of electronics hardware from the device, we can improve accessibility to care. In other words, reducing the cost of the medical device, strategic use of the computing horsepower within Smartphones, and prevalent accessibility to Smartphones will allow improved patient compliance and efficacy of the device as compared to other ECG event recorders currently on the market. Patients can perform an ECG recording almost anywhere and during normal daily activities without major interruption to their lives.



4. CLINICAL USE MODEL:

The *AliveCor Heart Monitor for iPhone* is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of User (medical professional or patient). In the hands of a medical professional, the *AliveCor Heart Monitor for iPhone* is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional.

In the hands of a patient using the device under the prescription of a physician, the *AliveCor Heart Monitor for iPhone* is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional.

The most common method of using the *AliveCor Heart Monitor for iPhone* is to hold the device such that the subjects left and right hands are in contact with the left and right electrodes on the back of the Case, see Figure 3. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the User can experiment to minimize muscle noise and maximize the ECG signal quality. Alternatively, for some subjects, the device may be held up directly to the chest for data acquisition, See Figure 4.



Figure 3: Handheld monitoring



Figure 4: Chest Placement on sternum

5. OPERATING PRINCIPLE AND DETAILED DESIGN DESCRIPTION:

In layman's terms, the *AliveCor Heart Monitor for iPhone* wirelessly communicates to the iPhone with human-silent, ultra-low power data transmission protocol. It has extremely accurate front end electronics with high resolution analog-to-digital conversion processed by the iPhone. The iPhone provides the computing horsepower for the App to digitally filter the data and process it to create a high resolution human readable ECG strip.

5.1. *AliveCor Heart Monitor for iPhone Case*

There are just two modes of operation for the Case, STANDBY and ON. In the STANDBY mode, the electronic circuitry is actively looking for a connection between the electrodes (impedance). When the Case detects presence of a conductive path between the electrodes (hands or skin contact), it turns ON and begins to emanate a modulated ultrasonic frequency (inaudible



pressure wave) with a piezo oscillator, see Figure 6. After the electrodes are removed from the conductive path, the Case returns to the STANDBY mode.

Figures 2 and 5 show both sides of the *AliveCor Heart Monitor for iPhone Case*. The “inside” holds the iPhone 4/4S very firmly and provides protection for the front and back glass top layers of the phones from accidental drops onto hard surfaces. The inside of the case also has a battery door with a small Phillips Head screw, which allows changing of the coin cell battery, see Figure 5.



Figure 5: Inner Case (battery cover in yellow)

(b) (4)

5.1.1. Hardware Design

(b) (4)



(b) (4)

A large, solid grey rectangular redaction box covers the majority of the page, obscuring the content of Figure 6.

Figure 6: Exploded View of Case



5.2. Apple iPhone 4/4S:

The frequency modulated ultrasonic ECG signal is acquired by the built-in microphone on the iPhone. The iPhone provides the computing ability to process the data as requested by the App.

Refer to the online specifications for the Apple iPhone 4/4S which is a state-of-the art, touch interface Smartphone with wireless connectivity to 2G, 3G, WiFi, Bluetooth and GPS radio systems.

<http://www.apple.com/iphone/iphone-4/specs.html>

<http://www.apple.com/iphone/specs.html>

Both the iPhone 4 and 4S these devices are of identical shape and size so they can both use the same *AliveCor Heart Monitor for iPhone Case*. Both versions of the Smartphone can operate using the latest version of the iOS operating system, iOS 5.1 or a later version, which is the only version supported by *AliveCor Heart Monitor for iPhone* system at this time.

5.3. Software Design *AliveCor Heart Monitor for iPhone App*:

(b) (4)

The *AliveCor Heart Monitor for iPhone App*:

- acquires the ECG data wirelessly from the case,
- displays the ECG data on the iPhone's screen,
- performs real-time filtering, including: (b) (4)
- detects the QRS complexes for calculation and display of the heart rate,
- records the unfiltered ECG waveform at a sampling rate of 300 samples per second (16-bit resolution) into the iPhone's memory,
- allows recording of identifying information with a timestamp of the recording,
- allows printing of the ECG rhythm strip report,
- allows secure (encrypted PDF) emailing of the ECG to a physician, and
- securely uploads (via SSL) ECG and other data to a secure web server for storage.

There is no programmability related to functionality of ECG acquisition, thus the device requires limited User interaction.

*More details of this element of the device can be found in the Software Design Description provided in Section 16.



6. ALIVECOR HEART MONITOR FOR IPHONE SPECIFICATIONS:

Performance Characteristics

ECG Channel	Single Channel
Input Dynamic Range	10mV Peak-to-Peak
Memory length	Practically Unlimited
Recording Format	Continuous
Shelf Life	Estimated 2 years

Circuitry

Frequency Response	0.5 Hz to 40 Hz
CMRR	76 dB
Input Impedance	> 100 MOhm
Differential Range	+/- 5 mV
A/D Sampling Rate	300 samples/second
Resolution	16 bit
DC Offset Correction	+/- 300 mV

Output

Modulation	Frequency Modulated Ultrasonic Audio Tone
Center Frequency	19 kHz
Frequency Deviation	200 Hz/mV

Power Requirements

Battery Type	1 Lithium Manganese-Dioxide 3V Coin Cell (CR2016)
Battery life	100 Hours Operational Time, 12 months typical use

Physical Characteristics

Dimensions	118 x 62 x 16.5 mm
Weight	40 grams

Environmental Specifications

Operational Temperature	+10 to +40 degrees C
Operational Humidity	10% to 95% (non-condensing)
Operational Altitude	maximum 3,000 meters (based on iPhone 4S)
Storage Temperature	-20 to +60 degrees C
Storage Humidity	10% to 95% (non-condensing)

Standards Compliance

ANSI/AAMI EC38	IEC 60601-1	IEC 60601-2-47
ISO 10993	IEC 60601-1-2	

Patient Interface

Two stainless-steel electrodes are exposed on the back of the *AliveCor ECG for iPhone Case*, which are either placed on the patient's chest or connected from left to right hand.



7. MATERIALS:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the Case, touching the stainless steel-electrodes, or replacing the battery.

Primarily two components of the Case may contact skin: the Front Case, and more significantly the stainless-steel electrodes. The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the Case for its utility purpose (as an iPhone case), and using the device for its medical purpose.

*The biocompatibility studies are presented in Appendix B and are summarized in Section 15.

(b) (4)

(b) (4)

Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products.

(b) (4)

. Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.



510(k) PREMARKET NOTIFICATION SUBSTANTIAL EQUIVALENCE DISCUSSION

1. SUBSTANTIAL EQUIVALENCE STRATEGY

To demonstrate substantial equivalence, two types of analysis are described herein:

- Standards test compliance
- Detailed predicate device comparisons based on electrical, mechanical and environmental specifications, provided in part 2 below.

2. CHOICE OF PREDICATE DEVICE

The options for choosing a predicate device for the AliveCor Heart Monitor for iPhone (device) are plentiful. For well over 20 years, ECG event recorders, of both the post event and looping variety, have transmitted real-time and stored ECGs as frequency modulated (FM) audio signals (e.g. Instromedix, Inc. King of Hearts - K880626)

More recently, due to advancements in technology, ambulatory ECG monitors have been iterating to reduce cost and size (e.g. iRhythm Technologies, Inc. Event Card - K081471) while some have increased in complexity and features (CardioNet, Inc. Ambulatory ECG Monitor with Arrhythmia Detection - K093288). A few have tried to simplify the use model for Over-the-Counter use (e.g. Card Guard Scientific Survival, LTD. King of Hearts Express + AF Monitor).

AliveCor, Inc. (AliveCor) chose the HeartCheck Pen Handheld Heart Rhythm with GEMS Home (K121009) marketed by CardioComm, Inc. for several reasons.

- The HeartCheck Pen has an Over-the-Counter (OTC) indication for use, of which AliveCor believes, after proper validation studies, our device may be resubmitted to obtain clearance for OTC.
- The HeartCheck Pen uses the identical product code (DPS) as the proposed device from AliveCor. This element was not a major factor in this decision, but
- The form factor and use model of the HeartCheck Pen is nearly identical to the proposed AliveCor Heart Monitor for iPhone.

3. STANDARDS COMPLIANCE

In this 510(k) submission, we have shown that proposed device is compliant to AAMI/ANSI EC38:2007. Via compliance with that recognized standard, we claim substantial equivalence by inference, as other devices in this classification should also comply with this standard, or an equivalent, and in particular the predicated device. Although we did not explicitly test the predicate device to EC-38 standards, we can infer substantial equivalence because the predicate device, in order to receive premarket approval, would have to have demonstrated equivalent performance. The same can be said for IEC60601-1 series tests for general safety and particular safety for ambulatory ECG monitors. The predicate device, to have received premarket clearance would have to have shown that it was in compliance with certain safety and electromagnetic compatibility standards.



4. PREDICATE DEVICE SPECIFICATION COMPARISONS

The following comparison table delineates the incremental difference between the approved HeartCheck Pen device and the proposed AliveCor Heart Monitor for iPhone. The table includes comparisons of the features and specifications of both devices, including electrical, mechanical, anatomical, and environmental characteristics. Any differences between the two designs have been marked with bold.

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Indications for Use:</i>	The HeartCheck™ Pen Handheld with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor ECG for iPhone is intended for use by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.
<i>Standards:</i> Essential Performance AECG Safety General Safety EMC Safety	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2
<i>Data Acquisition:</i> Frequency Response ECG channels Resolution Sample Rate	1 Hz – 40Hz Single Channel Unknown 250 Samples/Second	0.5 Hz – 40 Hz Single Channel 16 bit 300 Samples/Second



Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
Memory Capacity:	20 recordings	Essentially unlimited due to real-time transmission to iPhone memory
Device Classification:	DPS: Electrocardiograph	DPS: Electrocardiograph
Power Supply: Battery	2 AAA batteries	1 Lithium Manganese Dioxide Coin Cells
Battery Life (typical)	Unknown	100 hours operational
User Interface: Primary Lead Data upload Software interface	Lead I, Left to Right Hand USB PC based software	Lead I, Left to Right Hand Ultrasonic transmission iPhone OS based software
Physical Specs: Dimensions, inches Weight	130 x 30 x 20 mm 110 grams	118 x 62 x 16.5 mm 40 grams
Electrodes: Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel
Lead Wires:	None	None
Where used:	Ambulatory outpatient use	Ambulatory outpatient use
Prescribed:	Over-the-Counter	Prescription Only
Environmental: Operating Temp Storage Temp	5 to 40 degrees C -20 to 55 degrees C	10 to 40 degrees C -20 to 60 degrees C

The discussion below covers the areas in Table 1 where the designs diverge.

4.1. Indications For Use

The modification to the indications for use does not imply a change to the actual indication, but merely clarifies the predicate device indication. Most of the verbiage in the indications for the HeartCheck Pen is in AliveCor's opinion warnings/cautions that should be defined elsewhere as it is defined in our product labeling (See Section 13: Proposed Labeling).

4.2. Data Acquisition

The only difference among this group of specifications is that the predicate device has higher bandwidth cutoff at 1 Hz, versus 0.5 Hz for the AliveCor device. The AliveCor device, along with the majority of ambulatory ECG monitors follow the AAMI low-end bandwidth cutoff of 0.5 Hz. This has proven over the years to be adequate for quality ECG acquisition.

The sampling rate of the AliveCor device (300 Hz) is faster than the HeartCheck Pen (250 Hz). Faster sampling can potentially provide finer detail in the ECG rhythm strip, therefore the AliveCor device is substantially equivalent if not better than the predicate.



4.3. Memory Capacity

The AliveCor device transmits ECG data in real-time for storage on the iPhone non-volatile flash memory. Storing data on any handheld device is limited by the size of the on-board memory. The HeartCheck Pen uses onboard memory whereas the AliveCor device utilizes the vast memory capacity of the iPhone. This is essentially the same function, although the AliveCor device transmits to the iPhone before it stores, while the HeartCheck Pen stores before it transmits (via USB) only to store the data again on the PC.

4.4. Power Supply

The AliveCor device uses a single coin cell type battery, while the Heart Check Pen uses 2 AAA type batteries. Both of these batteries and battery chemistries are consumer off-the-shelf type batteries. Essentially there is no difference in power type. Lithium coin cell batteries are widely used in a variety of technologies and do not pose any significant safety hazards.

4.5. User Interface

The HeartCheck device use a USB cable and PC based software (GEMS Home) to upload, while the AliveCor device uses ultrasonic transmission and the iPhone Operating System.

The change from a USB cable to real-time acoustic data transmission is logical for this type of device. For well over 20 years, the industry has been sending acoustic ECGs by means of trans-telephonic data transmission (Instromedix, Inc. King of Hearts, iRhythm Technologies, Inc. Event Card, etc.). The AliveCor device is essentially performing the same action, but at an inaudible frequency range that the iPhone 4/4S microphone can receive.

(b) (4)





4.6. Physical Specs

Construction materials, size and weight differ slightly between the compared devices, although the general size and weight are very comparable. The AliveCor device takes on additional size to function as an iPhone case, but significantly reduces the weight due to the lack of hardware technology and batteries needed. Biocompatibility testing of all patient-contact materials has been performed and passed (see Appendix B: Biocompatibility Testing). There are no additional risks associated with the difference in physical specifications that affect the safety or efficacy of the device.

4.7. Prescription

(b) (4)

4.8. Operating Temp / Storage Temp

The upper and lower limits of the operational and storage temperature range are slightly different between devices. This is simply due to a difference in an option selected during the thermal conditioning used during the test. There are no safety or efficacy issues related to this difference in specification.

5. PERFORMANCE EQUIVALENCE TESTING

(b) (4)

6. CONCLUSION

Based on the qualitative and quantitative comparative analysis provided here, the proposed AliveCor Heart Monitor for iPhone device is found to be substantially equivalent to the predicate device, HeartCheck Pen Handheld Heart Rhythm with GEMS Home marketed by CardioComm, Inc.



510(k) PREMARKET NOTIFICATION

PROPOSED LABELING

(In accordance with 21 CFR 807.87e)

1. ALIVECOR HEART MONITOR FOR IPHONE LABELING

This section contains first official revisions of the AliveCor Heart Monitor for iPhone labeling. Included in this section are the following.

- AliveCor Heart Monitor for iPhone User Manual
- AliveCor Heart Monitor for iPhone Quick Start Guide

Note: the User Manual and Quick Start Guide are currently in text/copy format only. AliveCor intends on “branding” our literature prior to going to market. The contents will remain substantially the same upon revision for branding.

- AliveCor Heart Monitor for iPhone Product Label
- AliveCor Heart Monitor for iPhone EMC and Electrical Safety Declaration

Note: this declaration uses a model number of SE260. Subsequent to the testing, AliveCor revised the model numbering method, changing from SE260 to AC-001. These two identifiers are which is the previous but equivalent model number for AC-001

2. PREDICATE DEVICE LABELING

For comparison purposes, product labeling describing the predicate device is included:

- HeartCheck Pen Handheld ECG Product Brochure
- HeartCheck Pen Product Sell Sheet



AliveCor Heart Monitor for iPhone User Manual

NOTE: For the current information on your product please visit www.alivecor.com/manuals



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1. PRODUCT DESCRIPTION

The AliveCor™ Heart Monitor for iPhone® (Heart Monitor) is a mobile, clinical-quality electrocardiogram (ECG) recorder for use by both patients and physicians. Each ECG reading records at a varying duration you set – from 30 seconds to continuous. The software application can store thousands of recordings on your iPhone, and these recordings are also accessible to you on the AliveCor server. The device consists of three components:

- The Heart Monitor which snaps onto the iPhone® 4 or 4S only (iPhone) and contains sensors and electronics used to collect ECG data and transmit it to the iPhone.
- The AliveECG mobile application (App) used to collect, view, save, and wirelessly transmit the ECG data to the AliveCor server.
- A user-supplied Apple iPhone 4 or 4S. Note: the iPhone must be purchased separately.

This Heart Monitor enables the physician or patient to:

- Collect and view single-lead ECG data using the Apple iPhone 4 (iPhone).
- Store ECG data on the iPhone.
- Wirelessly transmit ECG data to the AliveCor online server.
- Access ECG data stored on the AliveCor server from anywhere in the world, and print the data or save it to a hard drive.

2. INDICATIONS FOR USE

The AliveCor Heart Monitor for iPhone is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

There are no known contraindications for the AliveCor Heart Monitor for iPhone, although care should be taken when utilizing the device on infants weighing less than 10kg. AliveCor does not recommend using on patients with a cardiac pacemaker or other implanted electronic devices.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.

3. INTENDED USER

The device is intended to be used by licensed medical professionals or by a patient under the care and supervision of a physician.

4. GENERAL SAFETY PRECAUTIONS

- The device should not be used in conjunction with water, or in a wet environment.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.



- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful reading may not be possible.
- Do not place this unit onto metal surfaces. This will deplete the battery.

5. STORAGE AND HANDLING

Do not store the unit in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the unit
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields

6. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions.
- This device measures heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Patients should always consult their physician if they notice changes in their health, regardless of recording results.
- Do not use this device with a defibrillator.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

7. MAINTENANCE

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using alcohol hand sanitizer before each use.



8. PREPARE THE ALIVECOR HEART MONITOR FOR IPHONE FOR USE

Preparing the AliveCor Heart Monitor for iPhone for use involves several brief steps:

8.1. Unpack the AliveCor Heart Monitor for iPhone

- Remove the AliveCor Heart Monitor for iPhone case from the box.
- Snap the AliveCor Heart Monitor for iPhone case onto the back of your iPhone, making sure to align the cutout on the case with the camera on the back of your phone.
- To remove the device from your phone, press gently but firmly on the iPhone camera through the hole in the case while holding the case. The iPhone should partially pop out of the case and be easily removed.

8.2. Download the AliveECG mobile application (app)

- Using your iPhone, access the App Store.
- Search for the app AliveECG. Download and install this app.

8.3. Set up an AliveCor account

You will use your AliveCor account to access, print and save your ECG data stored on the AliveCor server. Follow the instructions presented when you open the app for the first time. You can go back later and change your information if necessary.

8.4. Configure software settings

Access the Settings screen in the app, then tap on AliveECG to open the settings for this app.

- Set the Recording Duration. Recording duration is the maximum length of time AliveECG will record a single ECG rhythm. For example, if the recording duration is set to 30 seconds, AliveECG will automatically stop recording after 30 seconds of ECG data has been collected. The recording duration can also be set to Continuous, where the system will record ECG data as long as the user maintains proper electrode contact.
- Set the Mains Filter. The Mains Filter removes any mains interference from the ECG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- Link to your AliveCor account. Tap in the Email field and enter the email address you used to set up your AliveCor account. Tap in the Password field and enter the password for your AliveCor account. (see Set up an AliveCor account above)

9. COLLECT ECG DATA USING ALIVECOR HEART MONITOR FOR IPHONE

In order to obtain a good ECG reading, it is important that measurements are taken correctly. Before taking a measurement for the first time, read these instructions carefully and make sure you observe the following instructions each time you take a measurement.

1. Make sure the AliveCor Heart Monitor for iPhone case is properly attached to your iPhone.
2. Disconnect headphones, charger cables, or any other connected devices.
3. Clean the two electrodes with alcohol-based hand sanitizer.
4. Using your iPhone, launch the AliveECG app.



5. For a Lead I ECG rhythm, hold the system using two hands; the left hand should contact the electrode closer to the top of the phone, and the right hand should contact the electrode closer to the bottom of the phone. Recording will begin automatically when both electrodes make contact with skin; do not wear gloves. The green bars in the upper left corner of AliveECG indicate when there is a connection between the patient and the electrodes.

NOTE: The ECG rhythm will appear best when the Heart Monitor is held steady. It may be helpful to rest your arms on a flat surface to increase stability.

6. AliveECG will record the ECG rhythm for the selected Recording Duration (see Configure Software Settings above). When the recording is complete, the data will be saved to your iPhone. If you remove contact after 10 seconds but before the selected recording duration is complete, the ECG will be saved and you will be able to review it.

NOTE: If you remove contact before 10 seconds of recording has occurred, the ECG will not be saved, and you will not be able to review it.

7. After the recording finishes, you may move your finger across the screen to scroll through the ECG data that has been collected.
8. After recording is complete, you can tap the annotate button to add additional notes about the recording.
9. Finally, tap the Action button and tap Send to AliveCor.
 - If you wish to delete this ECG rhythm so that it is not saved to your iPhone, tap the trash icon in the bottom right of the screen.
 - In the event that the Heart Monitor was oriented improperly while the ECG rhythm was recorded, it may appear inverted. To correct the orientation, tap on the center of the screen, and tap Invert ECG in the bottom left.
10. When you are finished reviewing the ECG rhythm, tap the AliveECG action button to return to the capture screen or review other previous recordings. You may now initiate another ECG rhythm reading by touching the electrodes again.

10. VIEW PREVIOUSLY RECORDED ECG RHYTHMS ON YOUR IPHONE

- Launch the AliveECG app.
- Tap ECGs in the top right corner of the screen. You will see a list of all ECG rhythms which have been recorded using your iPhone (excluding any previously deleted.)
- Tap the ECG rhythm you wish to view.
- When you are done viewing your recorded rhythms, quit the AliveECG app.

11. VIEW ECG DATA THAT HAS BEEN TRANSMITTED TO THE SERVER

- On your web browser, go to <http://www.alivecor.com>.
- Enter your email address and the password you created when you set up your AliveCor account. Click Sign In.
- The ECG data you have collected and transmitted to the AliveCor server will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file. Click on the PDF symbol to the left of the data set you wish to view.

-OR-



- Click the box to the left of the data set you wish to view so that it is checked, then click View.
- A PDF document showing the ECG rhythm will appear. Use the buttons in the top left corner to print the data (first button) or save the data to your hard drive (second button).
- You can attach a saved PDF file to an email to share the ECG data.
- Click the back button to return to your AliveCor account homepage.

12. EDIT ECG DATA

There are three options for editing your ECG data. You can adjust the Mains Filter, Add a Comment, or Invert the ECG. To access these options, sign in to your AliveCor account, and click the box to the left of the data set you wish to edit so that it is checked; then click Edit and follow the instructions below:

12.1. Adjust the Mains Filter

- The Mains Filter removes any mains interference from the ECG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- Click Save.

12.2. Add a comment

- Add a comment to the text box and click Save. This comment will appear on the PDF.

12.3. Invert the ECG

- In the event that the AliveCor Heart Monitor for iPhone was improperly oriented when the ECG rhythm was recorded, it may appear inverted. The ECG rhythm may be adjusted to the correct orientation by inverting it.
- Click the box to the left of Invert ECG so it is checked and click Save.

13. REPLACE THE BATTERY IN YOUR ALIVECOR HEART MONITOR FOR IPHONE

The battery in the Heart Monitor should last approximately one year; however the actual life will depend on how often you use the device.

- Remove your iPhone from the AliveCor Heart Monitor for iPhone case.
- Using a small screwdriver, remove the screw and battery door from the center of the AliveCor Heart Monitor for iPhone case.
- Remove the used battery and replace it with a new CR2016 3V lithium manganese dioxide battery. Orient the battery with the positive terminal up, so that you can see the writing.

NOTE: Replacement batteries are available for sale at most drug stores.

- Replace the screw and battery door.
- Dispose of the used batteries according to the local law.



14. TROUBLESHOOTING

Problem	Solution
I do not see an ECG signal in AliveECG.	<p>Check that you have good contact with the electrodes. Clean the electrodes and clean and moisten the skin. Make sure the contact between the skin and the electrodes is not obstructed.</p> <p>If the problem persists, replace the battery in your AliveCor Heart Monitor for iPhone case. (See Replace the Battery in your AliveCor Heart Monitor for iPhone.)</p>
The ECG rhythm appears upside down.	<p>In the future, reverse the orientation in which you are holding the AliveCor Heart Monitor for iPhone. To invert an already recorded ECG rhythm on your iPhone, or on the AliveCor server, see Invert ECG under Edit ECG Data.</p>
I do not see the ECG rhythm on my AliveCor server account.	<p>Launch the AliveECG app on your phone, and tap ECGs. Tap the data set you would like to send to the server. When the data loads, tap the Action button, and tap Send to AliveCor.</p> <p>If you would like to send the data automatically once it is recorded, make sure that Auto Send is enabled. (See Configure Software Settings under Prepare the AliveCor Heart Monitor for iPhone for Use).</p> <p>If the problem persists, make sure your account username and password are correct. (See Configure Software Settings under Prepare the AliveCor Heart Monitor for iPhone for Use).</p>



15. ALIVECOR HEART MONITOR FOR IPHONE SPECIFICATIONS

Performance Characteristics

ECG Channel Single Channel
 Input Dynamic Range 10mV Peak-to-Peak
 Memory length Practically Unlimited
 Recording Format Continuous
 Shelf Life Estimated 2 years

Circuitry

Frequency Response 0.5 Hz to 40 Hz
 CMRR 76 dB
 Input Impedance > 100 MOhm
 Differential Range +/- 5 mV
 A/D Sampling Rate 300 samples/second
 Resolution 16 bit
 DC Offset Correction +/- 300 mV

Output

Modulation Frequency Modulated Ultrasonic Audio Tone
 Center Frequency 19 kHz
 Frequency Deviation 200 Hz/mV

Power Requirements

Battery Type 1 Lithium Manganese-Dioxide 3V Coin Cell (CR2016)
 Battery life 100 Hours Operational Time, 12 months typical use

Physical Characteristics

Dimensions 118 x 62 x 16.5 mm
 Weight 40 grams

Environmental Specifications

Operational Temperature +10 to +40 degrees C
 Operational Humidity 10% to 95% (non-condensing)
 Operational Altitude maximum 3,000 meters (based on iPhone 4S)
 Storage Temperature -20 to +60 degrees C
 Storage Humidity 10% to 95% (non-condensing)

Standards Compliance

ANSI/AAMI EC38	IEC 60601-1	IEC 60601-2-47
ISO 10993	IEC 60601-1-2	

Patient Interface

Two stainless-steel electrodes are exposed on the back of the *AliveCor ECG for iPhone Case*, which are either placed on the patient’s chest or connected from left to right hand.



16. RETURNS AND WARRANTY

14 Day Return Policy

The information on this page regarding return and warranty is intended for products purchased in the United States only. If you purchased the Heart Monitor (the "Product") directly from AliveCor, AliveCor's return policy allows you to return the Product within 14 days of receiving it. In order to be eligible for a full refund, the Product must be unopened, unused, undamaged, in its original condition, and in the original packaging; otherwise, a non-warranty refund may be refused, or you may be charged "open box" or restocking fees, as described below. An exchange or replacement Product can be requested if the Product's hardware is defective (see 1 Year Warranty policy below). In order for a non-warranty refund to be granted, a return merchandise authorization (RMA) number must be requested during the 14 day period following the date the Product was delivered. The RMA may be obtained by logging a support ticket at www.alivecorvet.com/support. In accordance with this policy, AliveCor offers a refund of the purchase price paid and will credit the account used to make the original purchase. AliveCor must receive the Product within 10 days after issuance of the RMA. In order to be eligible for a full refund, the Product must be packed in the original, unopened and unmarked packaging including any accessories, manuals, documentation, and registration that shipped with the Product.

For an opened or damaged Product, a \$30.00 open box fee will be assessed on any opened hardware or accessory, damage and missing part restocking fees may apply, or your refund may be refused.

Any shipping and handling charges you paid when you purchased the Product are not refundable. You are responsible for and must prepay all return shipping charges and you shall assume all risk of loss or damage to the Products while in transit back to AliveCor. If you return the Product to AliveCor (a) without a RMA from AliveCor, (b) beyond the 10 day RMA issuance period, or (c) without proper packaging, AliveCor retains the right to either refuse delivery of such return or charge you a restocking fee. The time to credit your account may vary, depending on processing time. Please allow a minimum of 4 weeks for AliveCor to credit the account used to make the original purchase. Product that was damaged by no fault of AliveCor is not returnable. If you purchased a Product directly from AliveCor that you received in damaged condition, please contact AliveCor's customer service at www.alivecor.com/support.

If you purchased the Product from a retailer other than AliveCor, please contact that retailer regarding non-warranty returns.

1 Year Warranty

AliveCor ("AliveCor") warrants the Heart Monitor (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of ONE (1) YEAR commencing on the date of the original purchase by the original purchaser (the Warranty Period). This warranty does not cover damage caused by misuse, accident, abuse, natural and/or external causes (i.e. fire, earthquake, flood, etc.), use other than as intended and described in the product instruction manual, finishes, normal wear and tear, tampering, unreasonable use, service performed by unauthorized service agencies, or loss or damage to batteries or removable parts. AliveCor does not warrant that the operation of the Product will be uninterrupted or error-free.



Limitation of remedies

Under this Limited Warranty, AliveCor's liability and customer's exclusive remedy under the foregoing paragraph will be limited to replacement or repair of the product by AliveCor or its authorized service centers. A replacement Product or part assumes the remaining warranty of the original Product or thirty (30) days from the date of replacement or repair, whichever is longer.

To obtain warranty service:

- Contact customer service at <http://www.alivecor.com/support>
- Write down the Return Merchandise Authorization (RMA) number given to you by a customer service representative.
- Repack the product with the packing slip in its original packaging.
- Include the RMA number in the following return shipping address:

AliveCor RMA #: (your RMA number)

1001 Montague Expressway

Milpitas, CA 95035

For your security, please return your product with an insured carrier (e.g., FedEx, UPS, USPS Parcel Post) and retain your receipt. AliveCor is not responsible for items damaged or lost in transit. Other than for the reason of hardware defects, the return freight cost responsibility belongs solely to the customer.

Limitation of damages

In no event will AliveCor or any of its affiliated or subsidiary companies be responsible for any special, incidental, or consequential damages resulting from the use of this product, or based on any breach of warranty, breach of contract, negligence, tort or any other legal theory. Such damages may include without limitation, loss of savings or revenue; loss of profit; loss of use; the claims of third parties, including without limitation retailers; any cost of any substitute equipment or services.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you. The warranty gives specific legal rights, and you may have other legal rights, which vary from state to state or country to country.

This Limited Warranty is valid only in the United States for Products sold in the United States. Resellers, agents, or employees of AliveCor are not authorized to make any modification, extension, or addition to this Limited Warranty.



17. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

140 Geary St., Suite 500

San Francisco, CA 94108

Toll-free: 888-473-1473

Online: <http://alivecor.com>



AliveCor Heart Monitor for iPhone

Quick Start Guide



NOTE: For the current information on your product please visit www.alivecor.com/manuals

1. PRODUCT DESCRIPTION

The AliveCor™ Heart Monitor for iPhone® (Heart Monitor) is a mobile, clinical-quality electrocardiogram (ECG) recorder for use by both patients and physicians. Each ECG reading records at a varying duration you set – from 30 seconds to continuous. The software application can store thousands of recordings on your iPhone, and these recordings are also accessible to you on the AliveCor server. The device consists of three components:

- The Heart Monitor which snaps onto the iPhone® 4 or 4S only (iPhone) and contains sensors and electronics used to collect ECG data and transmit it to the iPhone.
- The AliveECG mobile application (App) used to collect, view, save, and wirelessly transmit the ECG data to the AliveCor server.
- A user-supplied Apple iPhone 4 or 4S. Note: the iPhone must be purchased separately.

This Heart Monitor enables the physician or patient to:

- Collect and view single-lead ECG data using the Apple iPhone 4 (iPhone).
- Store ECG data on the iPhone.
- Wirelessly transmit ECG data to the AliveCor online server.
- Access ECG data stored on the AliveCor server from anywhere in the world, and print the data or save it to a hard drive.

2. INDICATIONS FOR USE

The AliveCor Heart Monitor for iPhone is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

There are no known contraindications for the AliveCor Heart Monitor for iPhone, although care should be taken when utilizing the device on infants weighing less than 10kg. AliveCor does not recommend using on patients with a cardiac pacemaker or other implanted electronic devices.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.

3. INTENDED USER

The device is intended to be used by licensed medical professionals or by a patient under the care and supervision of a physician.

4. GENERAL SAFETY PRECAUTIONS

- The device should not be used in conjunction with water, or in a wet environment.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.



- Do not use for any purpose other than obtaining an electrocardiogram.
- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful reading may not be possible.
- Do not place this unit onto metal surfaces. This will deplete the battery.

5. STORAGE AND HANDLING

Do not store the unit in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the unit
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields

6. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions.
- This device measures heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Patients should always consult their physician if they notice changes in their health, regardless of recording results.
- Do not use this device with a defibrillator.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

7. MAINTENANCE

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using alcohol hand sanitizer before each use.



8. PREPARE THE ALIVECOR HEART MONITOR FOR IPHONE FOR USE

- Unpack the Heart Monitor

CAUTION: Do not leave the two electrodes of the case face down on a metal surface, as this will drain the battery. It is best to leave the case face up when not in use.

- Snap the Heart Monitor onto the back of your iPhone 4 or 4S, making sure to align the cutout on the case with the camera on the back of your iPhone.
- Unpack the AliveCor Heart Monitor for iPhone
- Using your iPhone 4 or 4s, access the *App Store*.
- Search for the app *AliveECG*.
- Download and install the *AliveECG* App.
- Set up an AliveCor account. You will use your AliveCor account to access, print and save your ECG data stored on the AliveCor server. Follow the instructions presented when you open the app for the first time. You can go back later and change your information if necessary.

9. COLLECT ECG DATA USING ALIVECOR HEART MONITOR FOR IPHONE

In order to obtain a good ECG reading, it is important that measurements are taken correctly. Before taking a measurement for the first time, read these instructions carefully and make sure you observe the following instructions each time you take a measurement.

1. Make sure the AliveCor Heart Monitor for iPhone case is properly attached to your iPhone.
2. Disconnect headphones, charger cables, or any other connected devices.
3. Clean the two electrodes with alcohol- based hand sanitizer.
4. Using your iPhone, launch the AliveECG app.
5. For a Lead I ECG rhythm, hold the system using two hands; the left hand should contact the electrode closer to the top of the phone, and the right hand should contact the electrode closer to the bottom of the phone. Recording will begin automatically when both electrodes make contact with skin; do not wear gloves. The green bars in the upper left corner of AliveECG indicate when there is a connection between the patient and the electrodes.

NOTE: The ECG rhythm will appear best when the Heart Monitor is held steady. It may be helpful to rest your arms on a flat surface to increase stability.

6. AliveECG will record the ECG rhythm for the selected Recording Duration (see Configure Software Settings above). When the recording is complete, the data will be saved to your iPhone. If you remove contact after 10 seconds but before the selected recording duration is complete, the ECG will be saved and you will be able to review it.

NOTE: If you remove contact before 10 seconds of recording has occurred, the ECG will not be saved, and you will not be able to review it.

7. After the recording finishes, you may move your finger across the screen to scroll through the ECG data that has been collected.
8. After recording is complete, you can tap the annotate button to add additional notes about the recording.
9. Finally, tap the Action button and tap Send to AliveCor.



- If you wish to delete this ECG rhythm so that it is not saved to your iPhone, tap the trash icon in the bottom right of the screen.
- In the event that the Heart Monitor was oriented improperly while the ECG rhythm was recorded, it may appear inverted. To correct the orientation, tap on the center of the screen, and tap Invert ECG in the bottom left.

10. When you are finished reviewing the ECG rhythm, tap the AliveECG action button to return to the capture screen or review other previous recordings. You may now initiate another ECG rhythm reading by touching the electrodes again.

10. VIEW PREVIOUSLY RECORDED ECG RHYTHMS ON YOUR IPHONE

Previously recorded ECGs can be viewed within the *AliveECG* App or by logging into your account at www.alivecor.com

11. CHANGING SETTINGS IN THE MOBILE APPLICATION

You may adjust your *AliveECG* App settings from within the app by clicking on the *Settings* button in the bottom right-hand corner of the screen.

Description: AliveCor Heart Monitor for iPhone

REF AC-001 **SN** XXXXXXXX **RxOnly** **QTY: 1**

Rating:  3V 2.2mW **Battery:** CR2016

Manufactured for AliveCor, Inc.

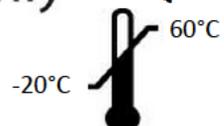
by IDT Technology Ltd.

 9/F, Kaiser Estate, Phase I, 41 Man Yue street, Hunghom, Kowloon, Hong Kong

Made in China



www.alivecor.com



02LB03.A

V1.0

A 2

Report No.: TRE11100035

**Guidance and manufacturer's declaration – electromagnetic emission –
for all EQUIPMENT AND SYSTEMS**

Row

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The SE 260 AliveCor Heart Monitor for iPhone is intended for use in the electromagnetic environment specified below. The customer or the user of SE 260 AliveCor Heart Monitor for iPhone should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions EN 55011	Group 1	The SE 260 AliveCor Heart Monitor for iPhone uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions EN 55011	Class B	The SE 260 AliveCor Heart Monitor for iPhone is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions EN 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions EN 61000-3-3	N/A	

**Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS**

Guidance and manufacturer's declaration – electromagnetic immunity			
The SE 260 AliveCor Heart Monitor for iPhone is intended for use in the electromagnetic environment specified below. The customer or the user of the SE 260 AliveCor Heart Monitor for iPhone should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SE 260 AliveCor Heart Monitor for iPhone requires continued operation during power mains interruptions, it is recommended that the SE 260 AliveCor Heart Monitor for iPhone be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the a. c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The SE 260 AliveCor Heart Monitor for iPhone is intended for use in the electromagnetic environment specified below. The customer or the user of the SE 260 AliveCor Heart Monitor for iPhone should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SE 260 AliveCor Heart Monitor for iPhone, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SE 260 AliveCor Heart Monitor for iPhone is used exceeds the applicable RF compliance level above, the SE 260 AliveCor Heart Monitor for iPhone should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SE 260 AliveCor Heart Monitor for iPhone.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM -
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the SE 260 AliveCor Heart Monitor for iPhone			
The SE 260 AliveCor Heart Monitor for iPhone is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SE 260 AliveCor Heart Monitor for iPhone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SE 260 AliveCor Heart Monitor for iPhone as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



*Unlocked view

Putting your heart health in your hands

Research has shown that regular ECG-based heart screening significantly reduces the risk of sudden cardiac death. Source: JAMA 2006 and Circulation 2012.

Using the HeartCheck™ PEN ECG device, you can now take heart readings the moment a symptom is felt. Whether at home, the gym, or at the office, the HeartCheck™ PEN is portable, easy to use, and takes accurate heart readings that can later be shared with a physician or HeartCheck™ ECG Coordinating Centre. Until now, monitoring this comprehensive would usually require a lengthy visit to a family physician or hospital.

With HeartCheck™ SMART Monitoring, you can enjoy the peace of mind of having your heart rhythm analyzed and interpreted by a physician, HeartCheck™ ECG Coordinating Centre, or both, at any time from anywhere in the world with an internet connection*

* The free GEMSTM Home software will need to be installed in order to upload your heart rhythm files containing your ECGs.

The first FDA-Cleared device that can be unlocked to allow consumers and patients to view and print their own ECGs.*



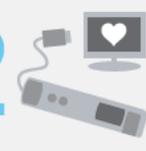
With the HeartCheck™ PEN device, it only takes 30 seconds to take a heart reading and the device can store up to 20 heart rhythms. Using a USB cable, simply connect the device to your PC and run the free GEMS™ Home software to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, can instantly view and analyze the results of your ECG and heart rhythm. This allows the physician or Coordinating Centre to identify any potential issues and provide the appropriate response.

for more information contact us today at
1 (877) 977.9425 or visit www.theheartcheck.com

how it works:

step 1  Using the HeartCheck™ PEN device, simply take heart readings the moment you feel any symptoms.

step 2  Using the USB cable provided, connect the device to your PC and run GEMS™ Home to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

step 3  Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, will view and analyze the results of your ECG and heart rhythms.

step 4  The HeartCheck™ ECG Coordinating Centre or physician will create an ECG report on your heart analysis identifying any potential issues.

The report will be made available on your PC through the GEMS™ Home application.

HeartCheck™ PEN Device

- ✓ *Cleared by the Food and Drug Administration (FDA)*
- ✓ *Easy to use*
- ✓ *Accurate heart readings in only 30 seconds*
- ✓ *Store up to 20 heart rhythms*
- ✓ *Unlock the PEN to view and print your own ECGs**
- ✓ *With SMART Monitoring, ECGs can be monitored remotely by a physician, clinic, or ECG coordinating center**



* The HeartCheck PEN Handheld ECG can be unlocked to display your ECG waveform by CardioComm Solutions, Inc. under the direction of a physician.



The HeartCheck™ Pen Device

Specifications

Powered by CardioComm Solutions, Inc.

Mechanical Specifications

Length: 130mm
 Width: 30mm
 Height: 20mm
 Weight: 110g (with batteries)

Technical Specifications

Lead Position: Lead I - Hand lead only
 Sampling Rate: 250Hz
 Measuring Range: 30bpm - 240 bpm
 Heart Rhythm Bandwidth: 1Hz - 40 Hz
 Measuring Accuracy: 30 - 100bpm: ± 2bpm
 101 - 240bpm: ± 4bpm

Display

Display screen type: OLED
 Parameter: Heart Rate
 * ECG option available when unlocked

Environmental Requirements

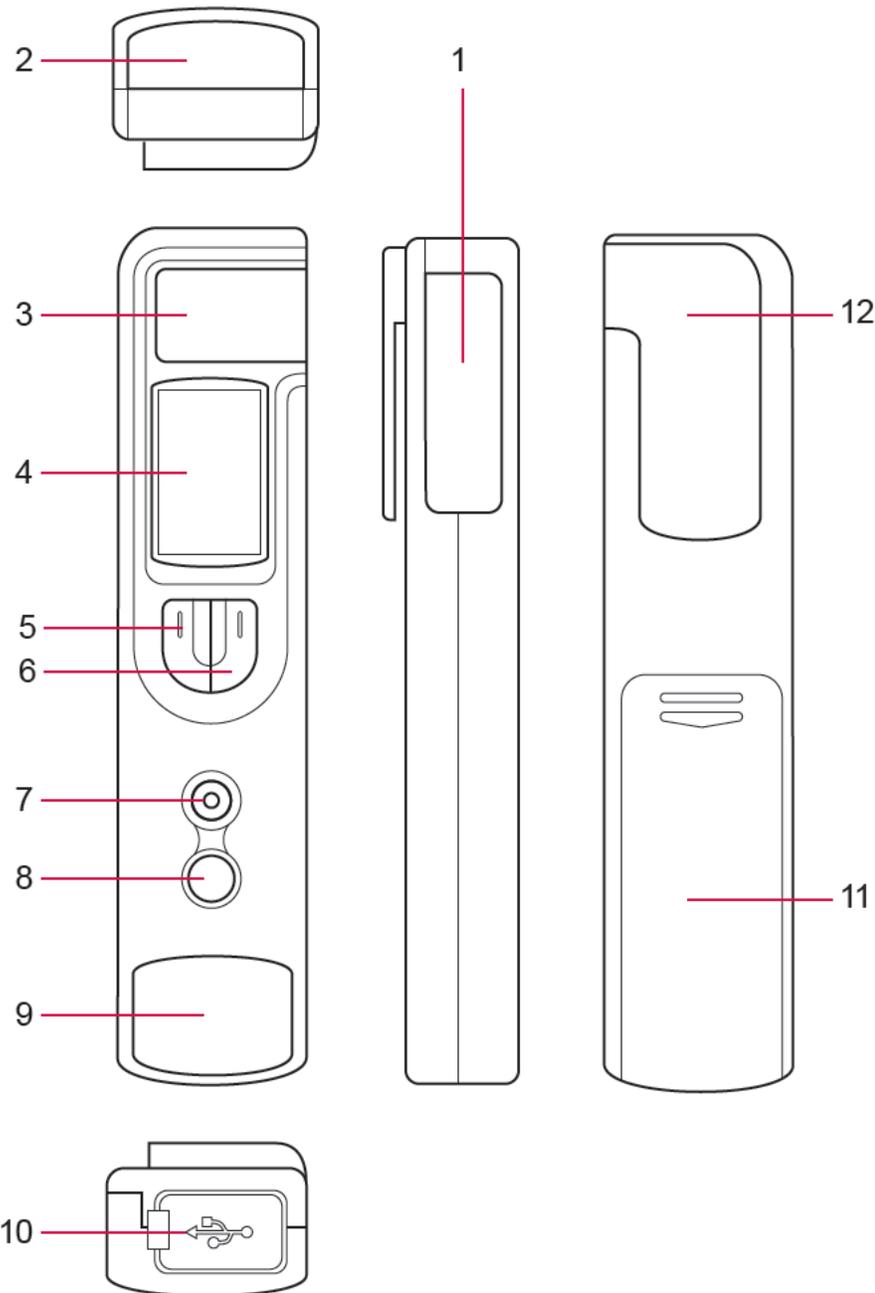
Operating temperature: 5°C - 40°C
 Storage temperature: -20°C - 55°C
 Operating humidity: ≤80%, no condensation
 Storage humidity: ≤90%, no condensation
 Atmospheric pressure: 80kPa - 106kPa

Power Supply

Batteries: 2 AAA A kaline batteries
 Protection type: Internally powered equipment
 Degree of protection: CF Type
 Safety: IEC 60601-1

Accessories

Standard Accessories: 2 x AAA A kaline batteries
 1 x Instruction Manual
 1 x Quick Operation Guide
 1 x Warranty Card
 1 x USB cable
 Data Management Software



* The HeartCheck heart rhythm monitor can be unlocked by CardioComm Solutions, Inc under the direction of a physician. Visit www.theheartcheck.com for details.

- 1. Right index finger electrode
- 2. Left index finger electrode
- 3. Right thumb electrode
- 4. Display screen
- 5. Scroll right button
- 6. Scroll left button

- 7. Power / Select button: Use this button to power on the device and/or select a menu item from the display screen
- 8. Start button: Use this button to start taking a heart measurement
- 9. Left thumb electrode
- 10. USB Port: Plug USB cable into this port to connect device to PC
- 11. Battery cover
- 12. Clip



for more information contact us today at

1 (877) 977.9425

or visit www.theheartcheck.com

the all new

Heart Check Pen 10

CardioComm Solution's new handheld Heart Check™ Pen gives you the benefit of quickly measuring your heart rhythm in just 30 seconds



- ✓ Very compact, portable and easy to operate
- ✓ Simply place your thumbs and index finger on the Heart Check™ Pen to see your heart rhythm
- ✓ 5 inches/ 130 mm in length and weighs only 3.8 oz/ 110 grams
- ✓ Saves 20 recordings of heart rate, data analysis and ECG
- ✓ Fast measurements in just 30 seconds
- ✓ Measure, record, and save or delete ECG waveform and Heart Rate
- ✓ Completely cable free
- ✓ Auto power-off
- ✓ Powered by two AAA batteries
- ✓ Transmit data to management software by USB cable

Heart Check
handheld ECG monitors

For more information contact:

 **CardioComm Solutions, Inc.**
259 Yorkland Road, Suite 200
North York, Ontario M2J 0B5

Toll Free 1 (877) 977.9425
Fax 1 (866) 576.4493

email: sales@cardiocommsolutions.com



**510(k) PREMARKET NOTIFICATION
STERILIZATION AND SHELF LIFE**

The *AliveCor Heart Monitor for iPhone* is provided non-sterile but assembled and packaged in a clean environment to eliminate particulate contamination. AliveCor's quality system and supplier management system ensure adherence to proper manufacturing conditions for the device. The *AliveCor Heart Monitor for iPhone* has no sterilization requirements.

Officially, verification testing was performed at time-zero product with fresh batteries. Verification testing has been completed following standard environmental preconditioning and transit testing. This evaluation yielded passing results and showed the *AliveCor Heart Monitor for iPhone* meets and exceeds all stated product requirements and that it conforms to applicable industry standards.

Additionally, battery testing and analysis was performed and proved that the device has a minimum operating time of 150 hours per the device specifications as defined in the Section 11 – Device Description. There are no critical device functions that deteriorate over time other than the battery life. The battery is a CR2016 coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries. AliveCor has retention samples that are planned for use for real-time shelf life testing.

Note: At this time AliveCor does not believe there is a reasonable shelf life limitation for the device. If a shelf life limitation is identified, AliveCor has unit level traceability that will allow us to retrieve expiring product. Subsequently, all further shipped product would be assigned an expiration date.

All results related to shelf life testing for the *AliveCor Heart Monitor for iPhone* can be found in the *AliveCor Heart Monitor for iPhone* System Level Requirements Verification Report (02SLRR), on file at AliveCor.



510(k) PREMARKET NOTIFICATION BIOCOMPATIBILITY ASSESSMENT

1. INTRODUCTION:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the Case or the stainless-steel electrodes.

The biocompatibility assessment for the *AliveCor Heart Monitor for iPhone* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the Case for its utility purpose (as an iPhone case), and using the device for its medical purpose. All testing was performed by a certified laboratory, using ISO-10993 guidelines.

2. DEVICE MATERIALS TESTED:

Primarily two components of the Case may contact skin: the Front Case, and more significantly the stainless-steel electrodes. The *AliveCor Heart Monitor for iPhone* is constructed differently than the predicate device; however, the primary patient-contact materials, are generally the same.

- (b) (4)

Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products including a primary use for Smartphone cases.

- (b) (4)

Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

Samples were constructed to include all materials from all parts of the device that may contact the patient, including incidental contact. The *AliveCor Heart Monitor for iPhone* Biocompatibility Test Sample drawings and specifications for material composition used in these test samples can be found in Appendix B – Biocompatibility Reports.



3. TEST METHODS:

To assess biocompatibility, the proposed patient-contact materials were subjected to the three standard tests for biocompatibility of medical devices for non-invasive long term wear (up to 30 days) on skin, as outlined in ISO 10993-1. These three tests were Cytotoxicity (MTT Method), Irritation (Animal intracutaneous reactivity test by means of polar extract), and Sensitization (GPMT), and were conducted by the Testing Center of Sanitation & Environment Technology Institute, Soochow University.

All three tests passed. See Appendix B – Biocompatibility Reports for the full test reports.

- The MTT Method Cytotoxicity test passed with a viability reduced to 81.7% minimum of all the samples where a passing viability is 70% or more. Under the conditions of this study, the test article did not show toxicity to L-929 cells.
- The Skin Irritation Test, conducted per ISO 10993-10:2010, passed with a Primary Irritation index of 0.0, where a score of 2 or greater is considered failing. The irritation response category for the test article was classified as slight.
- The Guinea pig maximization test (GPMT) Hypersensitivity, conducted per ISO 10993-10:2010, passed with the conclusion that no sensitization potential was observed.

AliveCor believes that the patient-contact materials proposed for use in the *AliveCor Heart Monitor for iPhone* meet the requirements for biocompatibility and can therefore be safely used in the proposed application.



510(k) PREMARKET NOTIFICATION

SOFTWARE

1. SOFTWARE – LEVEL OF CONCERN

Using methods described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued by FDA on: May 11, 2005, AliveCor, Inc. (AliveCor) has made the determination from the decision tree and tables that the Level of Concern is Moderate because malfunction or latent design flaws could lead to erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury of the patient. See document 02SWDD – ECG for iPhone Software Design Description, attached to this section.

The Moderate Level of Concern determination is consistent with our understanding of most if not all other ambulatory ECG Event Recorders on the market.

2. SOFTWARE REQUIREMENTS SPECIFICATION

Specific software requirements have been defined for the *AliveCor Heart Monitor for iPhone*. See document 02SLRS – ECG for iPhone System Level Requirements Specification, attached to this section.

Note that “ECG for iPhone” is an internal project name while the “*AliveCor Heart Monitor*” is the externally referenced project name. For all intents and purposes, these terms are equivalent.

3. SOFTWARE DESCRIPTION

An extensive description of the software written for the ECG for iPhone can be found in the Software Design Description. See document 02SWDD – ECG for iPhone Software Design Description, attached to this section.

The description includes an architecture design chart, identifies key modules with description of functionality, security design, user interface, other design features and a discussion of the software development environment, and implementation/deployment methods. Although not required for Moderate Level concern software, AliveCor chose to provide this as it meets many of the content requirements for this section.

4. SOFTWARE HAZARD ANALYSIS

Software Hazard Analysis is covered as part of the overall risk assessment. See Appendix A for the ECG for iPhone Risk Assessment and Hazard Analysis.

5. DESIGN VERIFICATION AND VALIDATION

The ECG for iPhone Design and Development Plan and Product Development Record outline and provide traceability for the necessary design verification and validation activities. These activities include evaluation of the device for its intended uses and validation of the end-to-end, manufacturing-to-patient flow. These protocols include validating elements of the software that cannot be verified. This process is part of Design Control and reviewed at scheduled Design Review Meetings. See Section 21 for conformance to Design Controls.



6. SOFTWARE VERIFICATION AND VALIDATION

In addition to the general verification activities for User Needs and System Level Requirements, specific protocols are in place for verifying elements of the software that can be demonstrated by test or inspection, on file at AliveCor. Reference 02SLRV – ECG for iPhone System Level Requirements Verification Plan and 02SWRV – ECG for iPhone Software Requirements Verification Plan noted in Section 21.

Custom software is validated during design validation (system level evaluation) – refer to 02UNRV – ECG for iPhone User Needs Validation Plan noted in Section 21. Off-the-shelf software is validated independently of the design validation. Each software package/module used in the device, used during design verification, or used as a development tool have been validated according to AliveCor's Quality Management System requirements for Software Validation. Reports are on file at AliveCor.

7. TRACEABILITY ANALYSIS

Each software requirement in 02SLRS correlates one-to-one to a verification method and result in the Requirements Verification Plan (02SLRV) and Requirements Verification Report (02SLRR), respectively. See Section 21 for a complete list of related Design Control documents.

8. CHANGE CONTROL AND CONFIGURATION MANAGEMENT

AliveCor Inc. has established procedures for Design Control and Software Design and Development. Both the Design Control and Software Design and Development Procedures follow a phased approach to development. The Software Design and Development procedure also defines the practices in place following commercialization under maintenance activities..

All design documents are considered controlled documents and thereby undergo review and approval prior to release. In the same way, software code is controlled and maintained in a code repository. Any changes made to the code during maintenance are evaluated and a test plan appropriate for the change, is defined. Any software bugs or anomalies are logged and evaluate to determine the level of risk posed by the bug. Software releases are approved through technical review, and revision history is tracked and documented by AliveCor's Change Tracking System (Document Control). As appropriate, risk assessment, hazard analysis, design requirements, verification plans and other necessary design control documentation will be revised with each software release.

Software releases are typically deployed with release notes describing necessary changes to the development environment that may necessitate revalidation of software. Regulatory and Quality sign-off on all official software releases. AliveCor has little control over releases implemented by Apple for the iPhone, but we believe we have a comprehensive test protocol to maintain seamless functionality of our software.

9. REVISION HISTORY

The information below describes the engineering revision history for the ECG for iPhone App software. Note that as initial development releases not intended for production or fielded use, these revisions have not been subject to the change control processes described above.



The table also contains known anomalies for each revision (driving subsequent revisions), with unresolved anomalies listed for the last revision.

(b) (4)





(b) (4)





(b) (4)



10. SUMMARY OF VERIFICATION RESULTS

The *AliveCor Heart Monitor for iPhone* App has been verified according to the system level requirements verification plan (02SLRV). For a detailed description of verification results, refer to ECG for iPhone System Level Requirements Verification Report (02SLRR), on file at AliveCor. All tests passed with zero deviations and the specifications have been fully verified. AliveCor believes the test methodology/protocol is strong enough to prove the safety and efficacy of the system using the iPhone 4/4S running iOS 5.1 only.

(b) (4)



11. UNRESOLVED ANOMALIES

There are zero open defects. (b) (4)



The unresolved anomalies identified in the latest release of the software do not affect the essential performance of the device, nor do they affect risk or safety to the patient. These anomalies will be addressed prior to implementation of the software for design validation or production release.

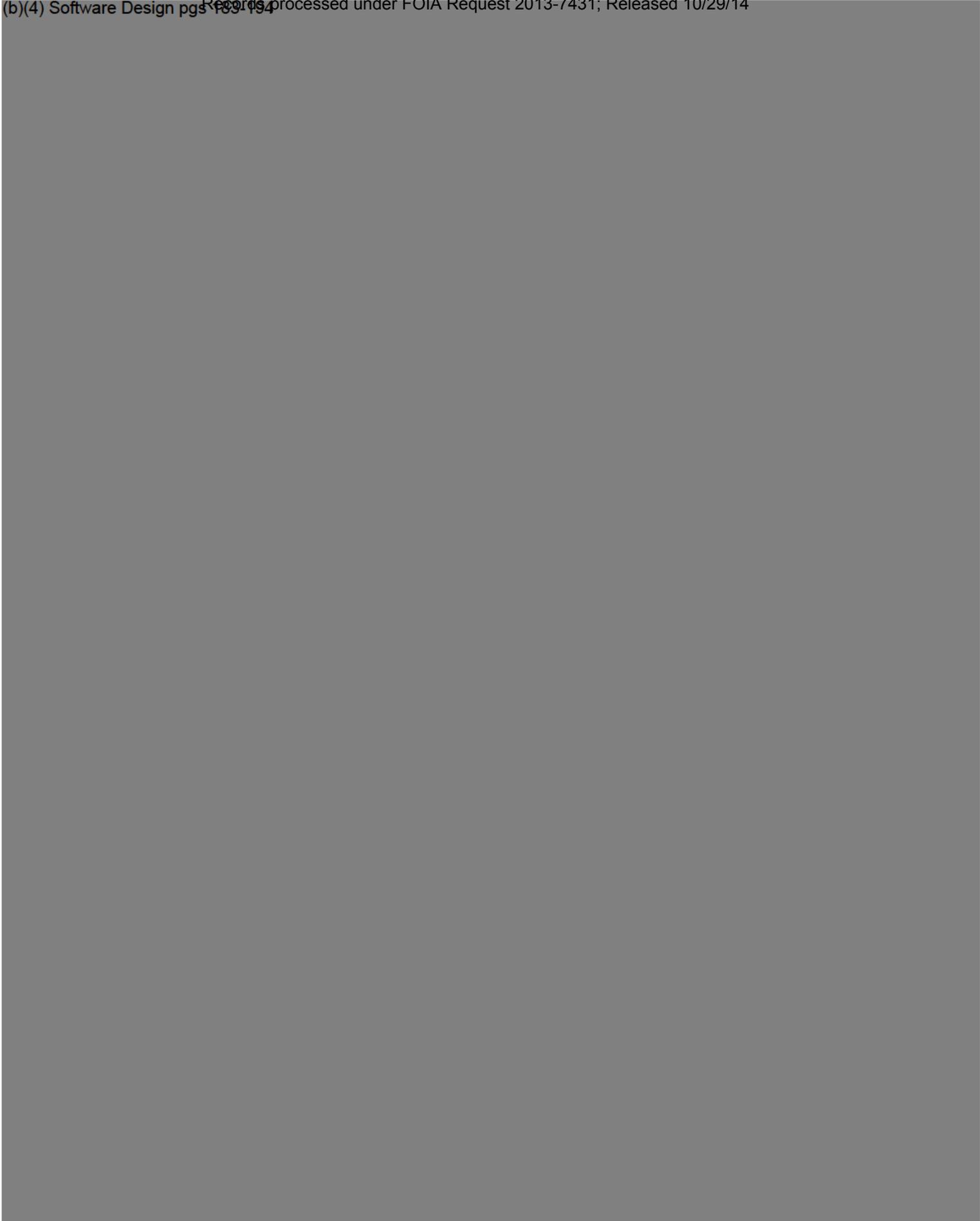
AliveCor, Inc. CONFIDENTIAL	Document #: 02SWDD	Rev: A	Page: 1 of 13
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TITLE:	ECG for iPhone Software Design Description
LOCATION:	Document Control\Design Control\ECG for iPhone
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Reviewed and Approved By:	Role	Name	Signature	Date
	Product Development	Bruce Satchwell		
	Software Development	Kim Barnett		
	Quality Assurance	Stephen Mordue		
	Regulatory Affairs	Michael Righter		
	Sales and Marketing	David McCaman		
	Clinical Operations	Dr David Albert		
	Document Control	David Peeler		

Change History

Revision	Date	Description of Change	Author
A	July 19, 2012	Initial version, incorporating System Architecture and Software design documents.	David Peeler



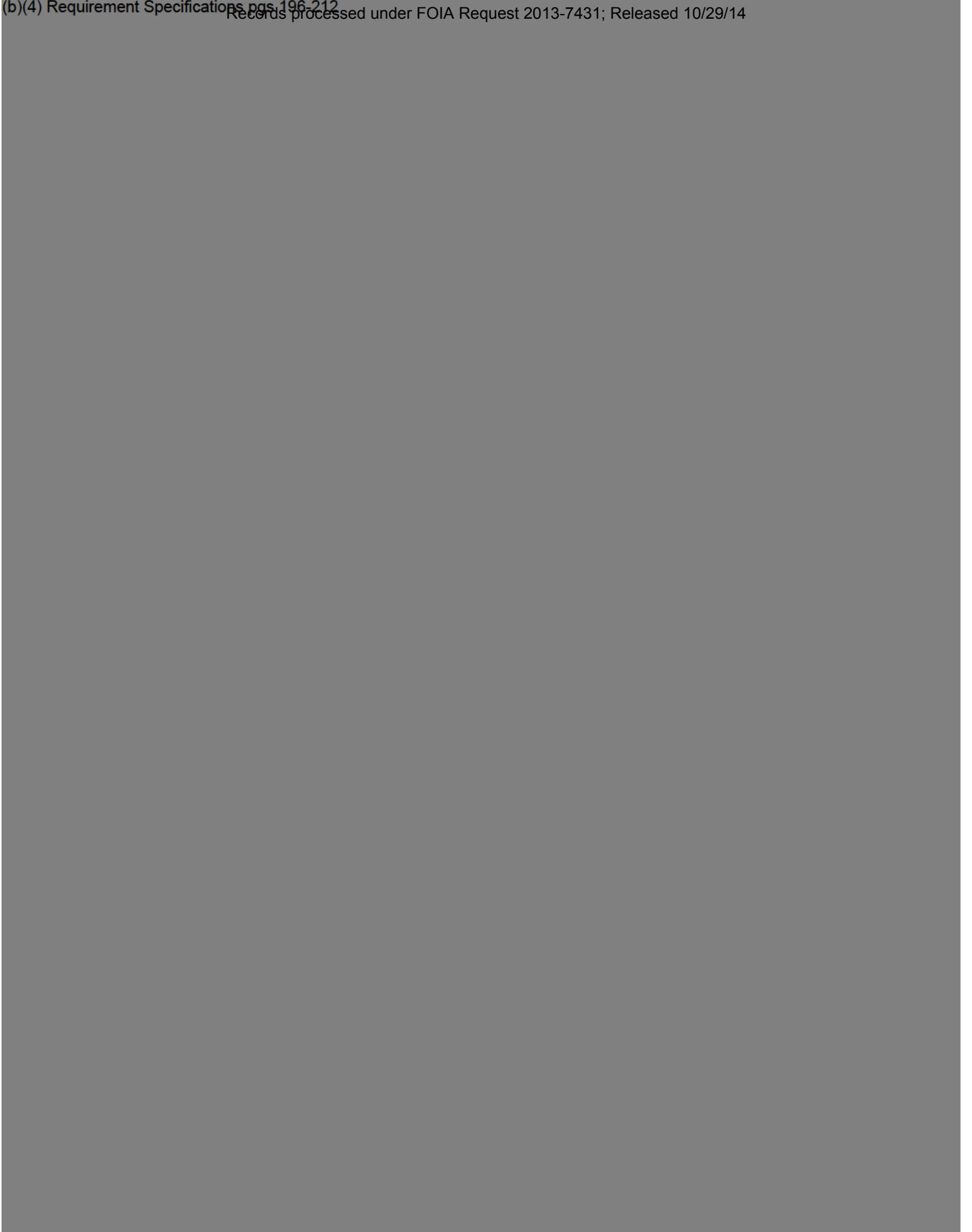
AliveCor, Inc. CONFIDENTIAL	Document #: 02SLRS	Rev: C	Page: 1 of 18
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TITLE:	ECG for iPhone System Level Requirements Specification
LOCATION:	Document Control\Design Documentation\ECG for iPhone
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	Role	Name	Signature	Date
Reviewed and Approved By:	Product Development	Bruce Satchwell		
	Software Development	Kim Barnett		
	Quality Assurance	Stephen Mordue		
	Regulatory Affairs	Michael Righter		
	Manufacturing Operations	Bruce Satchwell		
	Sales and Marketing	David McCaman		
	Clinical Operations	Dr David Albert		
		Document Control	David Peeler	

Change History

Revision	Date	Description of Change	Author
A	April 12, 2012	Initial version	Kim Barnett
B	May 1, 2012	Changes from review meetings of 18 April, 2012 and 25 April, 2012	David Peeler
C	July 19, 2012	Updated for AliveCor template Requirement 1810 changed to 1815	David Peeler





510(k) PREMARKET NOTIFICATION

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The *AliveCor Heart Monitor for iPhone* was evaluated for electromagnetic compatibility (EMC), including both emissions and immunity. We tested the device according to ANSI/AAMI/IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests to demonstrate the EMC characteristics of the device. The device was tested according to IEC 60601-1, ANSI/AAMI EC38 and ANSI/AAMI/IEC 60601-1-2 for patient safety.

Standard	Description
IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
ANSI/AAMI/IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests
ANSI/AAMI EC38	Medical Electrical Equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

The *AliveCor Heart Monitor for iPhone* has been designed to meet the set requirements of the above standards, and has been tested against those standards to assure compliance. Each applicable requirement from the individual standard has been translated to a specific requirement in design control documentation. Each of the requirements has been verified. A list of the verification activities are described in Section 21 and are on file at AliveCor. The majority of requirements related to EMC and Electrical Safety are contained within the AliveCor System Level Requirements Verification Report (02SLRR).

The Electrical Safety and Compatibility Information is in compliance with ANSI/AAMI/IEC 60601-1-2 is contained in the device labeling (see Section 13).

The Extent of Standard Compliance to each of these standards can be found in Section 9 of this submission.



**510(k) PREMARKET NOTIFICATION
PERFORMANCE TESTING - BENCH**

The following bench testing was performed on the AliveCor Heart Monitor for iPhone.

Full test protocols, results and conclusions are provided in the report location specified below, or on-file at AliveCor.

Description of Test	Standard	Test Report Located
System Level Requirements Verification Testing	02SLRV.A On-file at AliveCor	02SLRR.A On-file at AliveCor
General Safety	IEC 60601-1	Appendix C On-file at AliveCor
EMC Testing	ANSI/AAMI EC38, and 60601-1-2	Appendix D On-file at AliveCor
Environmental Testing	ANSI/AAMI EC38	Appendix D On-file at AliveCor
Biocompatibility Testing	ISO 10993-1	Appendix B On-file at AliveCor
Ambulatory ECG Safety Testing	ANSI/AAMI EC38 60601-2-47	Appendix E On-file at AliveCor
Real Life Radio Interference	N/A	Technical Report On-file at AliveCor
iPhone 4 GSM, 4 CDMA, 4S Hardware Compatibility	N/A	Technical Report On-file at AliveCor
Battery Capacity Evaluation	N/A	Technical Report On-file at AliveCor
Amplitude and Time Base Accuracy	N/A	Technical Report On-file at AliveCor
Performance Comparison to Omron HGC-801 Portable ECG Monitor	N/A	Technical Report On-file at AliveCor

All additional bench testing resulted in confidence that the AliveCor Heart Monitor for iPhone performs to the development team's expectations. No additional concerns related to safety and effectiveness resulted from the above testing.



**510(k) PREMARKET NOTIFICATION
PERFORMANCE TESTING – ANIMAL**

This section **does not apply**.



510(k) PREMARKET NOTIFICATION PERFORMANCE TESTING – CLINICAL

1. INTRODUCTION

This section typically would not apply for this regulatory filing, but significant clinical testing has been performed using prototype devices under IRB approval that provides some indication of design efficacy. AliveCor intends on conducting formal design validation post market clearance. The following information describes the studies performed, includes excerpts from the published abstracts and includes some commentary regarding the importance of these studies.

2. HAND-TO-HAND LEAD VALIDATION

The accuracy of the Lead I recording using the “hands” method has been validated in a published clinical study where 65 patients had both Lead I recordings from the *AliveCor Heart Monitor for iPhone* and from a 12-lead ECG using a GE MAC5500. The amplitude correlation between Lead I recordings from the *AliveCor Heart Monitor for iPhone* and GE MAC5500 devices (low pass filtering set to 40Hz) was $r = 0.997$, suggesting that the hand-to-hand lead orientation with the AliveCor device has clinical viability when compared to an industry standard piece of equipment. Two physicians independently validated the ECG waveforms from the 65 patients as equivalent.

AliveCor Heart Monitor for iPhone further tested our device in a clinical validation study of Lead I from the *AliveCor Heart Monitor for iPhone* versus Lead I from a standard 12-lead as recorded by a GE MAC5500. The results from that study have been published as an abstract at the 2012 Scientific Session of the Heart Rhythm Society (HRS). A summary of the results follows:

The mean/SD of the R-wave amplitudes for the GE MAC5500 Lead I and *AliveCor Heart Monitor for iPhone* Lead I recordings respectively were 0.77/0.24 (mV) and 0.78/0.24 (mV), which was not a significant amplitude difference under the Pearson Comparative Test ($r = 0.996$, $p < 0.0001$). Further, regression analysis resulted in a correlation single-tail probability of $z = 3.86$ ($p < 0.000569$) heavily suggesting a rejection of the null hypothesis that the similarity in recorded data between the two devices occurred entirely coincidentally.

The conclusion of the study was that “comparing recordings taken by the GE MAC5500 and the *AliveCor Heart Monitor for iPhone* produced no differences of a level considered clinically significant. The *AliveCor Heart Monitor for iPhone* device could and should be considered a valid tool for recording Lead I cardiac rhythm data for analysis by medical professionals. The iPhone-based Event Recorder is an accurate clinical tool for ECG assessment as a tool in instant rhythm analysis in situations where supplemental ECG data is necessary or useful or where more complex ECG devices are impractical.”

3. USER EXPERIENCE VALIDATION

The utility of the *AliveCor Heart Monitor for iPhone* device as an ECG Post Event Recorder for use by patients was evaluated in another published clinical study of 53 individuals who carried the device for two months with daily ECG recording and upload. Again the data was independently reviewed by two physicians for its clinical significance. While the study participants were not previously identified patients, several symptomatic and asymptomatic serious arrhythmias were identified in this group.



A total of 53 study participants consented to be study subjects and received the iPhone case. Of these, 49 (94%) sent in ECG transmissions and complied with weekly surveys (mean age, 43 ± 11 years, 77% male). The majority of ECG's were recorded from study subjects but 61% also handed their phones to others to enable them to record ECGs. Subjects reported using the device and under many different conditions from sedentary and alone to social situations with the intent to share with others.

The majority of participants (82%) reported that the device was beneficial, 33% felt that they were more health conscious after participating in the study and 88% thought that the device was transmitting accurate information. Participants indicated that they found the portability, ease of use, and the form factor to be the design aspects of the device that were most conducive to use.

Use of the device and ECG information caused 24% of subjects to reach out to their private physicians for a consultation and 16% felt that they discovered a health condition unknown to them with the device. The majority of participants (78%) wanted to continue to use the device after the 8 week study period.

The simplicity and availability of the technology tested in this study, present on the iPhone, provided our participants with a very low threshold for use and demonstrates that non-trained as well as trained medical personnel will use their iPhone to collect physiologic data. The patient case studies also demonstrate that disease detection is not uncommon. The importance of having the ability to detect conditions outside of the confines of a physician's office, using a device that is with people most of the time, is paramount to increasing the ability to diagnose and treat more patients. Physician prescribed Event Recorders offer a defined period of use and insurance coverage and are only made available to the public if a physician visit occurs, most commonly due to patient symptoms. The *AliveCor Heart Monitor for iPhone* could help break down barriers for patients to take their health into their own hands.

Ubiquitous ECG Recording: ‘Casual’ Wireless Cardiac Monitoring by AliveCor Smartphone Electrocardiograph Event Recorder Case Provides Previously Unobtainable Data and Yields New Insights

L. Saxon M.D.¹, D. Albert M.D.^{2,2}, A. Smith¹, S. Doshi¹, H. Tun MPH¹, J. Dinsdale², K. Albert²

¹ University of Southern California Keck School of Medicine, Division of Cardiovascular Medicine

² AliveCor Inc

Abstract:

The speed of wireless communication technology, particularly on the 3G network and the widespread adoption and use of iOS supported smart phones (Apple, Cupertino, CA, iPhone) provide the infrastructure for the transmission of wireless biomedical data anyplace, anytime.^{1,2}

One technology incorporates electrodes into an iPhone case and uses Bluetooth to transmit an ECG recording corresponding to a standard Lead I on a 12-lead ECG (AliveCor, Oklahoma City, OK,). A leadless 30 second ECG tracing is obtained by simply holding the iPhone and placing ones fingers on the electrodes embedded into the back of the case on the phone (Figure 1). The ECG tracing can be downloaded for immediate interpretation on any browser.³

This study has 60 participants, each of whom was provided an **AliveCor** iPhone ECG case. The Center for Body Computing (CBC) has found that users collect heart rate data an average of 35 times a week from this device, a huge use rate for a consumer product. The CBC thinks this is an incredibly powerful technology because of the ubiquity of smart phones, price point of the case, and ability to connect or feed the heart rate data into both into personal home healthcare⁴.



Figure 1-A: The electrodes are embedded in the back of the iPhone case.



Figure 1-B: An ECG is obtained by holding the device in hand or by placing it on chest.

Purpose and Environment of Investigation:

In order to study and determine consumer use cases for this technology, cases were provided to iPhone users attending a yearly conference on Body Computing at the University of Southern California. All participants provided informed consent⁵ and agreed to fill out baseline and weekly online surveys for eight weeks. ECG recordings were reviewed daily by the principal investigator, a board certified electrophysiologist.

Protection of private medical data was done utilizing the encryption technology that is FIPS 140-2 validated and stored on the AliveCor Secure Cloud Server. Each Recorded ECG was analyzed by both Dr. Leslie Saxon, a board certified electrophysiologist, as well as Dr. David Albert for quality, and normality of cardiac rhythm and heart rate.

Study Results:

A total of 53 study participants consented to be study subjects and received the iPhone case. Of these, 49 (94%) sent in ECG transmissions and complied with weekly surveys (mean age, 43± 11 years, 77% male). Study subjects represented diverse professions (15% physicians, 61% business, 13% media/entertainment, 11% engineers). Over the 8 weeks of the study, subjects transmitted an average of 36±53 30-second ECG recordings weekly (range 3-298). The majority of ECG's were recorded from study subjects but 61% also handed their phones to others to enable them to record ECGs.

Subjects reported using the device and under many different conditions. A total of 81% used the device casually and while alone, to determine their heart rate during varying emotional and physical conditions. Most (88%) used the device in social situations to show others. Symptoms such as rapid heart rate or a sensation of an irregular heartbeat prompted at least one transmission in 87% of subjects. ECG's were recorded at work in 64% of subjects.

The majority of participants (82%) reported that the device was beneficial, 33% felt that they were more health conscious after participating in the study and 88% thought that the device was transmitting accurate information. Participants indicated that they found the portability, ease of use, and the form factor to be the design aspects of the device that were most conducive to use. A minority of subjects (41%) reported use of other wireless or non-wireless health monitoring devices such as calorie trackers, scales, blood pressure cuffs or body fat monitors.

Use of the device and ECG information caused 24% of subjects to reach out to their private physicians for a consultation and 16% felt that they discovered a health condition unknown to them with the device. The majority of participants (78%) wanted to continue to use the device after the 8 week study period.

A total of 1768, 30-second ECGs were adjudicated. Transmitted ECG interpretation was normal sinus rhythm in the majority of recordings (68%). Sinus bradycardia or sinus tachycardia was present in 16% of recordings, extra atrial or ventricular systoles in 2% of recordings, and QRS delay greater than 120 msec was detected in (1%). A total of (13%) of recordings were not interpretable due to noise or motion artifact on the tracing.

Clinical Cases:

Detection of significant abnormalities that prompted intervention by the reviewing physician occurred in 3/53 subjects.

The first subject transmitted an average of 4 recordings weekly that demonstrated normal sinus rhythm and sinus tachycardia. The twenty third transmission revealed a wide complex tachycardia consistent with monomorphic ventricular tachycardia at 240 bpm (Figure 2). Upon review of this recording two hours after the event, the reviewing physician contacted the subject by phone. He identified himself as a 35 year-old businessman with no history of palpitations, syncope or other health problems. While in his car, he experienced new onset palpitations after lifting weights at his gym and felt lightheaded. He had his phone and transmitted the tracing. The episode lasted approximately 3 minutes, terminating abruptly. The initiation and termination of tachycardia was not recorded. A normal sinus rhythm reading was recorded immediately after tachycardia termination. Based on these tracings and the recommendation of the reviewing physician, the subject is now undergoing cardiac evaluation.

The second subject is not a study participant. He is a Nigerian male in his late thirties who was attending a business reception in Mumbai India on mobile health. At a reception, a study participant, a businessman who was attending the conference, met the Nigerian man at the reception and invited him to record his ECG on the device. The recording showed marked ST-T segment depression consistent with acute ischemia (Figure 3). Upon review of the tracing 13 hours after transmission, the reviewing physician contacted the study participant in Mumbai with her concerns and he was able to identify and contact the individual. The Nigerian man reported a history of cardiac disease, and was asymptomatic when the tracing was recorded, but after notification that the tracing was abnormal, noted that he planned to get immediate follow-up.

The third subject is not a study participant. She is a female in her early twenties and a college varsity tennis player. The subject was partnering a study participant when she collapsed on the court and began to show symptoms of sudden death. The participant used the device to take an immediate chest reading on the young woman. The subject displayed supraventricular tachycardia and a heart rate of 240 bpm (Figure 4). Upon seeing this, the study participant, a board certified cardiologist and electrophysiologist, performed carotid massage, decreasing the subjects symptoms. The subject informed the study participant that this was not the first episode she had experienced, but that she had previously seen two cardiologists, neither of whom found any diagnosable condition.

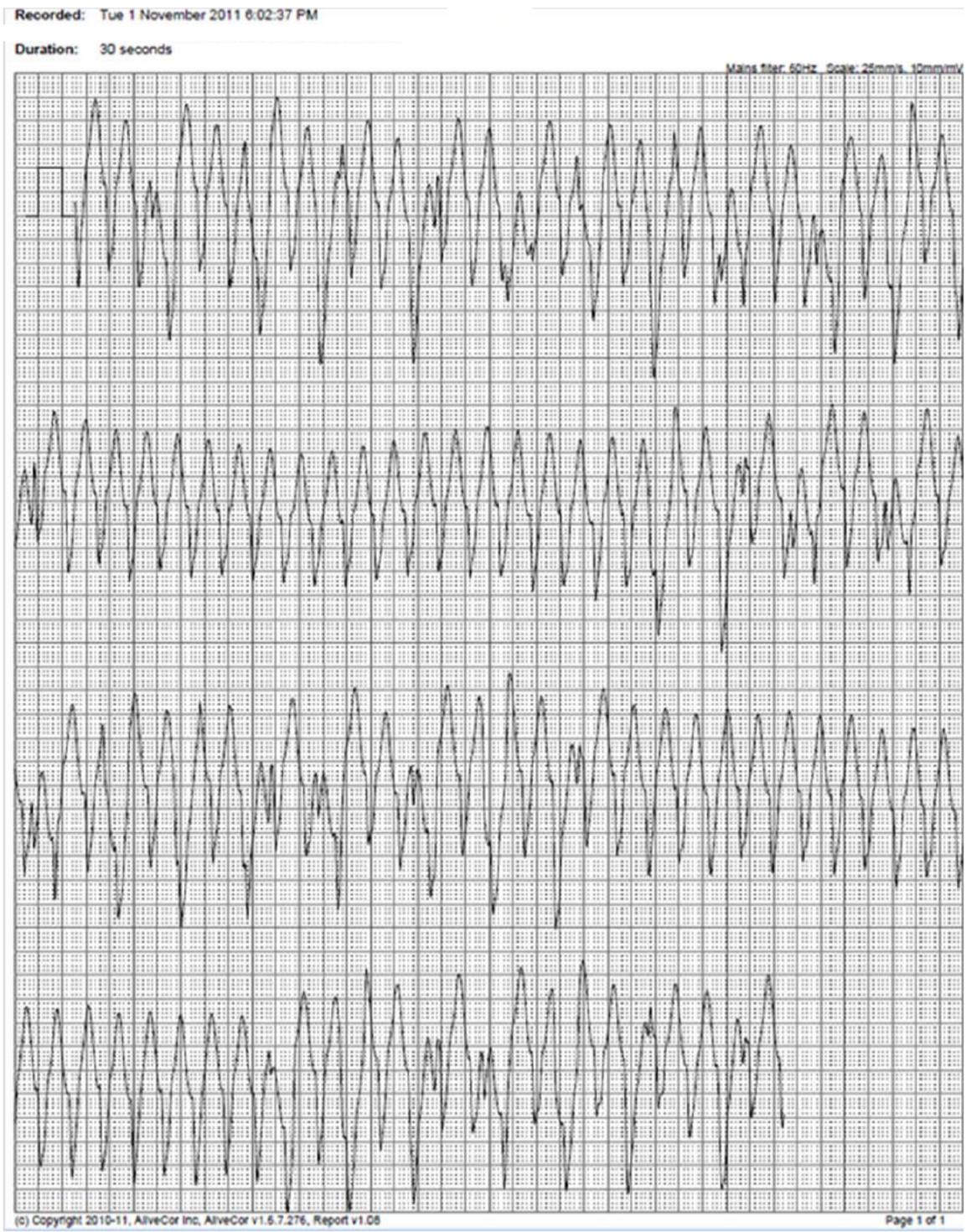


Figure 2-A: Initial thirty second recording of monomorphic ventricular tachycardia at a cycle length of 240 msec.

2

Recorded: Tue 1 November 2011 6:04:08 PM

Duration: 30 seconds

Mains filter: 50Hz Scale: 25mm/s, 10mm/mV



Figure 2-B: Ninety seconds later a second transmission demonstrates persistence of the tachycardia.

Recorded: Tue 1 November 2011 6:05:10 PM

Duration: 30 seconds

Main filter: 60Hz Scale: 25mm/s, 10mm/mV



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Figure 2-C: A third transmission immediately after the tachycardia terminated shows normal sinus rhythm.

Figure 3

Recorded: Sat 12 November 2011 7:15:42 PM

Duration: 30 seconds

Main filter 50Hz Scale: 25mm/s, 10mm/mV



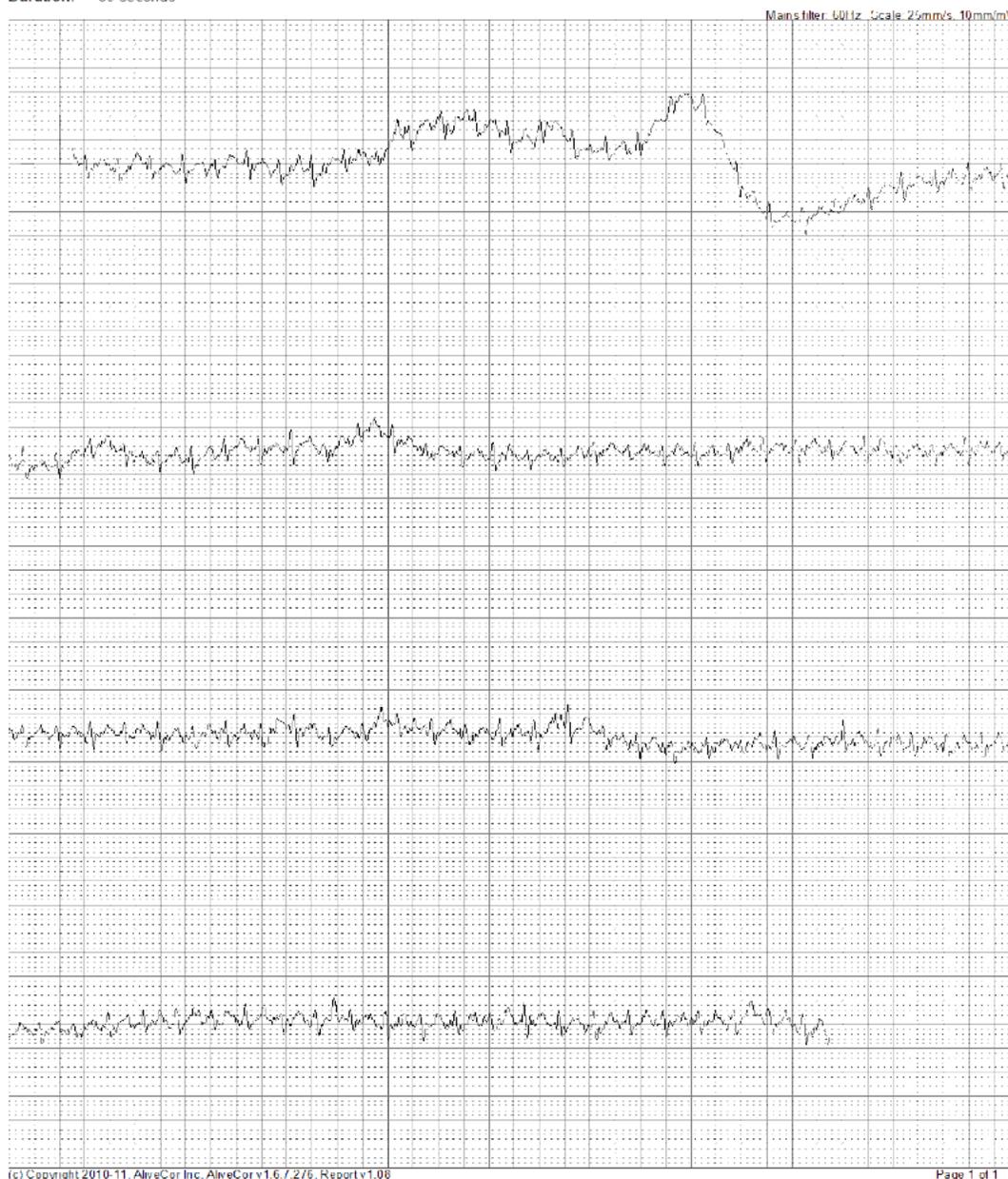
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Figure 3: 30 second transmission in an asymptomatic male showing normal sinus rhythm and marked ST-T wave depression consistent with cardiac ischemia.

Name: Leshe Saxon
Recorded: Mon 28 November 2011 8:27:41 PM
UDID: 881/a6284d2bdbc001193b49d438f2b3/b21ba34
Duration: 30 seconds

Comments:
SVT TENNIS PLAYER



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Figure 4-A: Initial display of supraventricular tachycardia and elevated heart rate of 240 bpm.

Name: Leslie Saxon
Recorded: Mon 26 November 2011 8:29:18 PM
UDID: 881/a6284d2bdbc001193b49d43852b3/b21ba34
Duration: 30 seconds
Comments: SVT TENNIS PLAYER



Figure 4-B: Capture after carotid massage has been performed. Heart Rate now lowered to 120 bpm.

Conclusions:

The simplicity and availability of the technology tested in this study, present on the phone, provided our participants with a very low threshold for use and demonstrates that non-trained as well as trained medical personnel will use their smart phone to collect physiologic data. The patient case studies also demonstrate that disease detection is not uncommon. The importance of having the ability to detect conditions outside of the confines of a physician's office, using a device that is with people most of the time, is paramount to increasing the ability to diagnose and treat more patients. Physician prescribed event recorders offer a defined period of use and insurance coverage and are only made available to the public if a physician visit occurs, most commonly due to patient symptoms.

Sudden cardiac death accounts for over 5% of annual mortality in the U.S. and often occurs in persons without known heart disease.⁶ The majority of events are due to arrhythmic causes in the setting of coronary ischemia, but the cause is due to an inherited arrhythmia syndrome, or undetected structural heart disease in up to 30% of patients.⁷⁻⁹ In our first case study, documentation of ventricular tachycardia at the time of occurrence was critical. It is not hard to imagine that an otherwise very healthy 35 year-old male complaining of one episode of abrupt onset/offset palpitations with light-headedness would not be suspected of having a sustained ventricular arrhythmia. It may be that what we consider minor symptoms in individuals with low risk profiles actually correlate with significant arrhythmias. Conversely, with ubiquitous ECG monitoring availability, we may detect what we consider to be major arrhythmias in many more individuals without known structural heart disease or risk factors. Similarly, detection of asymptomatic myocardial ischemia, a condition much more common than symptomatic ischemia, enabled by ubiquitous ECG recording, has enormous potential to identify large populations of patients at risk. Early detection of abnormalities provides a window of diagnostic and therapeutic opportunity for intervention to prevent significant cardiac events.⁹

Use of other features present in the smart phone, such GPS, could add further value to the device application by providing the location of the user should a significant arrhythmia occur that requires immediate intervention. There is also a clinical precedent for wirelessly collecting cardiac rhythm data in large numbers of patients who have implanted cardiac rhythm management devices such as pacemakers and defibrillators. We estimate that over 1,000,000 patients with implantable defibrillators transmit device data from home over protected networks daily.¹¹ Analysis of this data allows care providers to diagnose and treat issues as they arise rather than at routine follow-up visits. The data also provides new insights into arrhythmia occurrence and device behavior over much larger populations than those studied in clinical trials.¹²

While smart phone manufacturers have little interest in having smart phones fall under medical regulatory scrutiny, there are ancillary medical products, such as the case used in this study, and software applications that have successfully obtained FDA and/or European CE mark clearance for medical use.¹³⁻¹⁵ These include glucometers for diabetes management and software that ports data from the monitored hospital setting to the physicians' smart phone.^{14,15} Moreover, mobile carriers, like AT&T are devoting new business units and resources to understanding what additional capability is required to accommodate biomedical data collected and delivered over mobile devices and enabled by software applications.¹⁶

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¹² Saxon LA, [Hayes DL](#), [Gilliam FR](#), [Heidenreich PA](#), [Day J](#), [Seth M](#), [Meyer TE](#), [Jones PW](#), [Boehmer JP](#). Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. 2010; 122(23):2353-5.

¹³ Dolan, Brian. Apple Puts Onus of FDA Clearance on iPhone Developers. MobiHealthNews, 2009. <http://mobihealthnews.com/2641/apple-puts-onus-of-fda-clearance-on-iphone-developers/>.

¹⁴ AirStrip Technologies. <http://www.airstriptechnology.com/>

¹⁵ AgaMatrix. <http://www.wavesense.info/company>

¹⁶ AT&T for Health. <<http://www.att.com/gen/press-room?pid=18708>>.

Statements of financial interest by clinical investigators:

Leslie Saxon, M.D. - Dr. Saxon has never received compensation from AliveCor, nor is she an investor in AliveCor.

Alexandra Smith - Ms. Smith has never received compensation from AliveCor, nor is she an investor in AliveCor.

Han Tun, MPH - Mr. Tun has never received compensation from AliveCor, nor is he an investor in AliveCor.

Sona Doshi - Ms. Doshi has never received compensation from AliveCor, nor is she an investor in AliveCor.

David Albert M.D.- Dr. Albert is a founder and significant shareholder as well as an employee of AliveCor.

Kathryn Albert - Ms. Albert is a paid employee of AliveCor.

Jessica Dinsdale - Mrs. Dinsdale is a paid employee of AliveCor.

Evaluation of the Accuracy of the AliveCor Heart Monitor for Smartphone Through Comparison of Lead I Recording to a Standard 12-Lead ECG Recording Device

D. Reynolds M.D.^{1,2}

D. Albert M.D.³

K. Albert³, P. Garabelli M.D.^{1,2}, J. Dinsdale³

¹ Oklahoma University Health Sciences Center, Department of Internal Medicine Cardiovascular Medicine

² Veterans Affairs Medical Center of Oklahoma City, Department of Cardiovascular Diseases

³ AliveCor Inc

Evaluation of the Accuracy of the AliveCor Heart Monitor for Smartphones Through Comparison of Lead I Recording to a Standard 12-Lead ECG Recording Device

K. Albert¹, P. Garabelli M.D.^{2,3}, J. Dinsdale¹, D. Albert M.D.^{1*}, D. Reynolds M.D.^{2,3*}

¹ AliveCor Inc

² Oklahoma University Health Sciences Center, Department of Internal Medicine Cardiovascular Medicine

³ Veterans Affairs Medical Center of Oklahoma City, Department of Cardiovascular Diseases

* Primary Investigators

Abstract:

This study evaluated the accuracy of ECG recordings captured by a smartphone based low cost cardiac event recorder, The AliveCor Heart Monitor for Smartphones, through comparison to a FDA cleared, commonly used 12-lead ECG recording device within a clinical setting.

Recordings of participant Lead I ECGs were captured by both a standard 12-lead ECG device with gel-based electrodes (Mac5500, GE Healthcare) and by the single lead device with left and right hand metal electrodes (AliveCor). The recordings for each patient from the two devices were compared for QRS morphology and R-wave amplitude. For the majority of patients, both devices provided clinically equivalent Lead I measurements.

The mean and standard deviation of R-wave amplitudes for the two devices were calculated and evaluated for significant difference using a Student's t-test and bootstrapped with a Pearson analysis on the Student's t-test. The mean and standard deviation of the R-wave amplitudes for the 12-lead standard and AliveCor Heart Monitor recordings were respectively 0.770/0.244 (mV) and 0.775/0.236 (mV). The difference in amplitudes between the devices is of neither practical, nor statistical significance ($P < 0.0001$, $r > 0.996$).

The results of this study demonstrate that the AliveCor Heart Monitor for Smartphones is an accurate clinical tool for ECG assessment with important implications as a tool in instant rhythm analysis.

Purpose of Investigation:

The aim of the study is to demonstrate that the AliveCor Smartphone ECG Case generates rhythm strip data that meets the clinical quality requirements for accurate cardiac rhythm diagnosis, as defined by industry standard 12-lead ECG equipment. This is investigated by recording and comparing the Lead I rhythm data from the AliveCor ECG to Lead I rhythm data from a standard 12-lead ECG device over a final study group of 62 participants.

Environment of Investigation:

Prior to commencement of investigation, approval for the study was sought from and conferred by the Institutional Review Board of the Oklahoma University Health Sciences Center (OUHSC), of which the Veterans Affairs Medical Center in Oklahoma City, OK (VAMC) is a member institution. The AliveCor Chief Scientific Officer, Dr. David Albert, partnered with the Chief of Cardiovascular Medicine at the VAMC, Dr. Dwight Reynolds as primary investigators, in compliance with OUHSC policy requiring internal supervision of all research conducted on premises. A written description of planned protocol and an assessment of patient risk were provided to OUHSC. The AliveCor study qualified for expedited review and approval under the provisions that a) no biological sampling would occur¹ and b) the medical device utilized was noninvasive and not radiologically active.² The AliveCor ECG was considered “noninvasive” as it has been tested to and complies with the following medical equipment safety and performance standards:

- IEC 60601-1:2005 / ANSI/AAMI ES60601-1:2005
Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2- 47:2001 / ANSI/AAMI EC38:2007
Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.

Protection of private medical data was done utilizing the VA approved encryption technology that is FIPS 140-2 validated.

The data collection was completed over the four-day period of November 29th-December 2nd, 2011 at the VAMC Electrocardiograph Station by AliveCor Clinical Associates. All patients receiving scheduled or unscheduled 12-lead ECGs required for personal medical treatment at the VAMC were considered eligible study participants.

Methods:

The VAMC personnel recording the patient’s 12-lead ECG orally presented each potential participant with the study aims and methods. If the patient affirmed interest in participating in the study, then an AliveCor Clinical Associate again presented the investigative aims and methods to the participant. The AliveCor Clinical Associate then provided Informed Consent and Authorization for Release of Protected Health Information (PHI) for Research forms to the participant for written recording of participant informed consent.

Each participant was then assigned a de-identified ID consisting of an integer and a color. This ID was written at the top of the consent form and used to label all copies of the participant’s ECG data and utilized in any subsequent referencing of that patient data. The integers were assigned in ascending, sequential order, and the color adjunct was used to identify which Clinical Associate took the recording to control for acquisition operant error.

A printed copy of the participant’s earlier captured 12 lead ECG, under a 40Hz filter, was then provided to the AliveCor Clinical Associate by the VAMC personnel who acquired it.

With the iPhone in Airplane mode operating in Apple iOS version 4.2.1 and nested in the AliveCor Heart Monitor, the Research Associate then launched the AliveCor ECG software application.

In view of the participant, the Research Associate cleaned the AliveCor ECG electrodes as well as the associate's hands using an aerosolized solution of 0.7 ethanol.

The AliveCor ECG was placed into the hands of the study participant,



Figure 1: AliveCor Heart Monitor for iPhone 4/4s rear Contact Surface with Steel Electrodes

with a single hand on each electrode, allowing the device to take an automatic recording in Lead I position of 30 seconds duration.

When the recording was finished, it was annotated with the study ID of the participant.

After the final recording was taken on each collection day, each research associate switched the iPhone in their possession from airplane into normal mode and manually transmitted each recording to the AliveCor secure server.

The Lead I recordings made by the AliveCor ECG were accessed on the server in pdf format, and printed on a networked AliveCor printer in the medical standard format of 25mm/s at 1cm/mV.

Once data analysis was complete, each participant's consent and PHI release authorization forms, as well as all paper copies of ECG data were stored in a locked cabinet in Dr. Dwight D. Reynolds' office.

Results and Analysis:

Recordings captured by the AliveCor ECG from a participant were discarded from analysis if one of the recordings did not contain a minimum of four consecutive distinct QRS complexes. 69 individuals initially agreed to participate in the study. Prior to analysis, two individuals withdrew their consent for use of the data. Of the remaining 67 individuals, 66 participants had data that passed the pass/fail criteria. The discarded individual had a severe manual tremor

that prohibited clear recording at Lead I. Four of the study participants had verified implanted cardiac devices, which artificially determine heart rhythm. The data of these participants was segregated to control for the influence of Non-ECG devices in the capture of heart rhythm and rate data. The remaining participant pool consisted of 3 females and 59 males. Participant age ranged from 26 to 85 years with a mean age of 61. The mean age for the male participants was higher than that of the female participants at 62 compared to the female mean of 58 years of age.

For each qualifying participant, the printed recordings of the Lead I data from the 12 lead ECG and the AliveCor ECG were rendered semi-transparent through use of back lighting and overlaid to visually assess morphological similarity. A pass/fail criteria was determined wherein the apex of the p and t waves and the Q, R, and S inflection points of the recordings were required to appear to overlay exactly to the unaided eye to be considered "passing". All recordings passed this inspection. The AliveCor Heart Monitor's handgrip contact points resulted in more baseline noise, presumably due to electrode impedance and tremor as compared to gel electrodes.

The longer excursion of the first two QRS complexes for Lead I on the printed copy of the 12 lead ECG for each participant was measured to the nearest tenth of a millimeter and the length recorded. For each participant, on the printed copy of the AliveCor Lead I ECG, the matching excursions to those assessed on the 12 lead ECG were measured on a corresponding pair of QRS complexes. (See Appendix A)

The directed difference in excursion length between the standard and AliveCor ECGs was calculated for each participant and recorded.

The mean and standard deviation of the R-wave amplitudes for the standard and AliveCor Heart Monitor recordings respectively were 0.77/0.24 (mV) and 0.78/0.24 (mV), which was not a statistically significant amplitude difference under the Pearson Comparative Test ($r=0.996$, $p<0.0001$). Further, regression analysis resulted in a correlation single-tail probability of $z=3.86$ ($p<0.000569$) heavily suggesting a rejection of the null hypothesis that the similarity in recorded data between the two devices occurred entirely coincidentally.

The recordings for study participants that maintained an amplitude difference ≥ 1 mm universally had a QRS amplitude ≤ 4 mm [Figure 2], a short length. This suggests a possible link to the ambiguity of small complexes and the variation found between the devices' recordings.

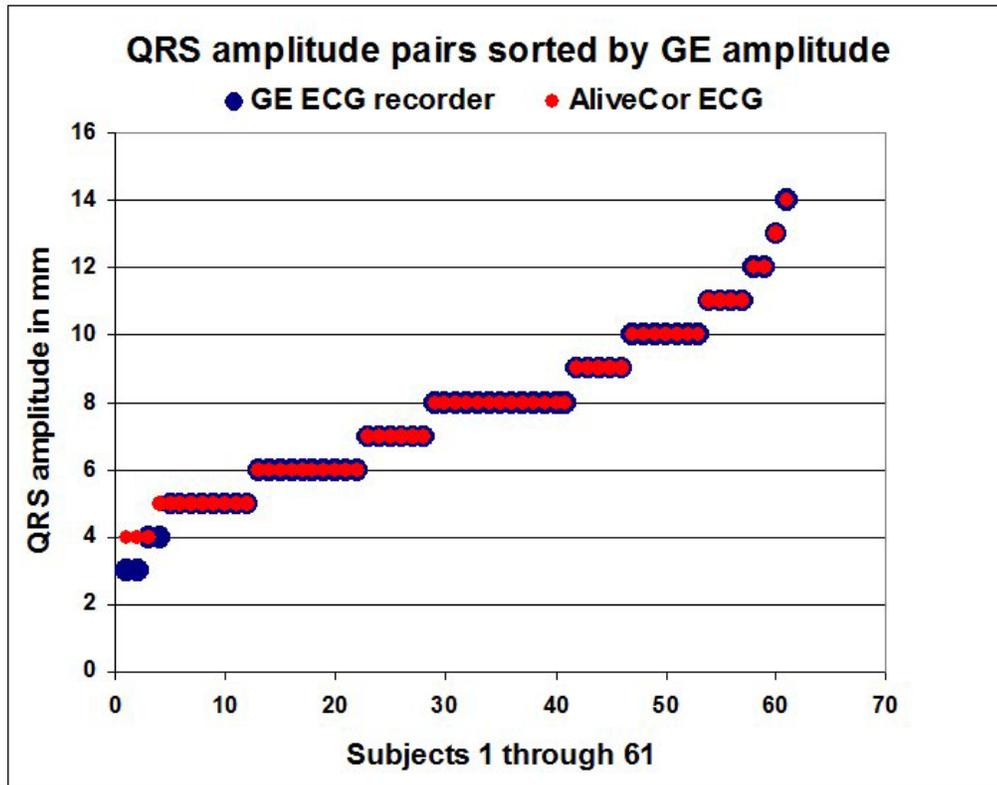


Figure 2: Comparison of R-wave amplitude between recordings taken by the standard and AliveCor devices by patient and length

Conclusions:

For several years, the GEMAC 5500 has held FDA clearance as a cardiac rhythm event recorder with the expectation of that it is being used for a valid diagnosis of heart activity and cardiac conditions³. Comparing recordings taken by this device and the AliveCor Heart Monitor produced no differences of a level considered either statistically or clinically significant. The AliveCor ECG device could and should be considered a valid tool for recording Lead I cardiac rhythm data for analysis by medical professionals. The AliveCor Heart Monitor event recorder is an accurate clinical tool for ECG assessment as a tool in instant rhythm analysis in situations where supplemental ECG data is necessary or useful or where more complex ECG devices are impractical.

¹ Criteria for Expedited Review under 45 CFR 46, The OUHSC Institutional Review Board Section 1a. http://www.ouhsc.edu/irb/IRB_Documents_Other/expeditedlist00.htm

² Criteria for Expedited Review under 45 CFR 46, The OUHSC Institutional Review Board Section 4a and 4b. http://www.ouhsc.edu/irb/IRB_Documents_Other/expeditedlist00.htm

³ FDA 510k number K073625 issued December 21st, 2007

Statements of financial interest by clinical investigators:

Dwight Reynolds M.D. - Dr. Reynolds has not received compensation from AliveCor, nor is he an investor in AliveCor.

David Albert M.D.- Dr. Albert is a founder and significant shareholder as well as an employee of AliveCor

Kathryn Albert - Ms. Albert is a paid employee of AliveCor.

Jessica Dinsdale - Mrs. Dinsdale is a paid employee of AliveCor.

Paul Garabelli M.D. - Dr. Garabelli has not received compensation from AliveCor, nor is he an investor in AliveCor.

APPENDIX A: Table of Comparative Participant R-wave Amplitude in mm by Device

Participant ID	GEMAC	AliveCor	Difference
1R	6	6	0
2R	12	12	0
3R	6	6	0
4R	6	6	0
5R	3	4	1
6R	6	6	0
7R	9	9	0
8R	6	6	0
9R	7	7	0
10R	9	9	0
11R	3	4	1
12R	11	11	0
13R	8	8	0
14R	9	9	0
15R	7	7	0
16R	7	7	0
17R	10	10	0
18R	5	5	0
19R	8	8	0
20R	10	10	0
21R	11	11	0
22R	11	11	0
24R	6	6	0
1T	12	12	0
2T	8	8	0
1G	5	5	0
3G	10	10	0
4G	7	7	0
5G	8	8	0
6G	5	5	0
7G	8	8	0
8G	8	8	0
10G	6	6	0
11G	5	5	0
12G	10	10	0
13G	7	7	0
14G	10	10	0
15G	8	8	0
16G	11	11	0
17G	8	8	0
18G	9	9	0

19G	6	6	0
20G	12	12	0
22G	5	5	0
23G	8	8	0
24G	9	9	0
25G	8	8	0
26G	7	7	0
27G	14	14	0
28G	6	6	0
29G	6	6	0
30G	4	4	0
31G	10	10	0
32G	4	5	1
33G	8	8	0
34G	5	5	0
35G	8	8	0
36G	5	5	0
37G	13	13	0
38G	5	5	0
40g	10	10	0
41g	8	8	0

APPENDIX B: Comparison of Participant Lead I Rhythm Strips



Lacy, Frank

From: Lacy, Frank
Sent: Thursday, September 20, 2012 8:50 AM
To: mike@alivecor.com
Cc: Lacy, Frank
Subject: K122356
Attachments: 122356e-mailhold.frk.doc

Mr. Righter,

Please find the attached Additional Information request. The instructions for processing your response are contained within the attachment.

If you have any questions, please feel free to contact me.

Regards,
Frank Lacy

September 20, 2012

Hello Mr. Richter:

I am the lead FDA reviewer for your 510(k) device application (K122356) review. I am sending this question to you via e-mail in an effort that this will facilitate your review and reduce response time. **Please answer the following questions by sending all of your correspondence through the Document Mail Center and not to me.** Please be advised that you should place the 510(k) number on all correspondence as well as be reminded that this file will be placed on HOLD until your responses are received. Receipt of your responses, by the agency, will continue the 90 day review cycle.

If you have any questions, please feel free to contact me via e-mail or at (301) 796-6321.

THIS E-MAIL IS INTENDED ONLY FOR THE PARTY TO WHOM IT IS ADDRESSED. IF YOU RECEIVE THIS MESSAGE IN ERROR, PLEASE RETURN TO SENDER. THANK YOU.

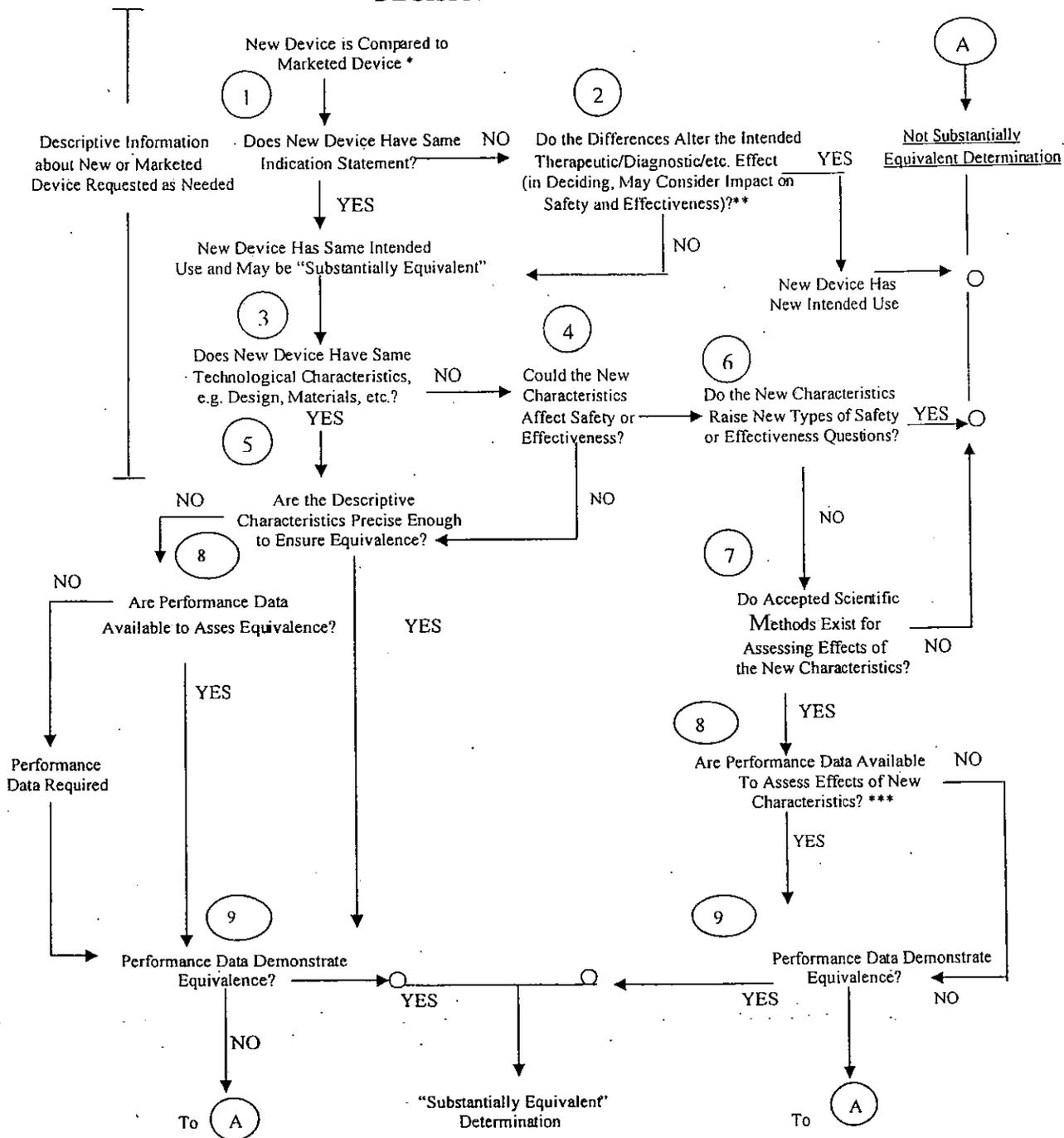
Question(s) for the manufacturer:

1. Please address the proprietary applications (APPs) by discussing the minimum recommended hardware and software requirements. Include in your discussion, the potential issue with smartphone OS software is that OS upgrades can render previous applications non-functional (apps that worked on the previous OS do not work with the new OS). Therefore, backward compatibility may be an issue even with minimum requirements.
2. Your 510(k) submission includes a reference to wireless communication. Wireless communication can change the risk profile of the device and thus FDA recommends that you address safety and effectiveness concerns for the use of RF wireless technology in your device. Wireless coexistence is the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules. Wireless coexistence issues are not adequately addressed via the IEC 60601-1-2 standard nor any other current standards. To address these concerns properly the sponsor should define all functions which will be implemented wirelessly, speak to the likelihood of other wireless devices operating in the same vicinity as your device and perform reasonable testing with such devices. In addition, if the sponsor foresees multiple copies of your device to be operated in the same area then this situation should also be included in the testing. A brief summary of the wireless coexistence testing should include the following points:
 - a. Define all functions to be implemented wirelessly. Describe safeguards and redundancy for the wireless function and possible risks associated with function failure.
 - b. Discuss how the RF antenna could affect other functions of the device.
 - c. Detailed information of the RF wireless technology implemented on your device. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for your device. Also include whether other devices (medical or non-medical) can operate on the same network and explain steps chosen to minimize coexistence problems.

- d. Explain all devices to be included in the coexistence test plan and justify their choice and how they represent a worst case scenario. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for all the interfering devices.
- e. Explain the pass/fail criteria for your device and the interfering devices with justifications on how these criteria were chosen and how they will be quantified and measured. Important parameters to keep in mind while testing are data integrity (ensuring proper function performance) and latency (ensuring functions occur within a timely fashion).
- f. Explain how the wireless coexistence testing was performed and how the testing addresses the possible risks from other wireless devices. Important parameters are separation distances, number of interferers, location, orientation, etc.
- g. Proper labeling should be included not only in a user manual, but also on the device itself cautioning users about the risks associated with the use of RF wireless technology and what can be done to mitigate possible interference issues.

Sincerely,
Frank Lacy; frank.lacy@fda.hhs.gov
Electrical Engineer
US Food and Drug Administration

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

NOV 19 2012

Alivecor, Inc.
c/o Mr. Michael Righter
Director, Regulatory Affairs
140 Geary Street, Suite 500
San Francisco, CA 94108

Re: K122356
Trade/Device Name: Alivecor heart monitor for iphone
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: October 18, 2012
Received: October 20, 2012

Dear Mr. Righter:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Page 2 – Mr. Michael Righter

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Owen P. Faris -S

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

Enclosure

Page 3 – Mr. Michael Righter

Concurrence & Template History Page
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K122356

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	 Owen P. Faris -S 2012.11.19 16:12:13 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format



510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K122356

Device Names: AliveCor Heart Monitor for iPhone

Indications for Use:

The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use X

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

AND/OR

(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)

Owen P. Faris -S

2012.11.19

16:09:42 -05'00'

* * * COMMUNICATION RESULT REPORT (NOV. 20. 2012 12:20PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : FILE MODE	NOV. 20. 2012 12:18PM OPTION	ADDRESS	RESULT	PAGE
1146 MEMORY TX		914153970440	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-0609
Silver Spring, MD 20993-002

NOV 19 2012

Alivecor, Inc.
c/o Mr. Michael Righter
Director, Regulatory Affairs
140 Geary Street, Suite 500
San Francisco, CA 94108

Re: K122356
Trade/Device Name: Alivecor heart monitor for iphone
Regulatory Number: 21 CFR 870.2340
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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Frank Lacy
Subject: 510(k) Number K122356
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (**SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>	X	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			*

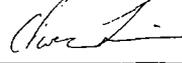
conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age<=21		
Neonate/Newborn (Birth to 28 days)		
Infant (29 days -< 2 years old)		
Child (2 years -< 12 years old)		
Adolescent (12 years -< 18 years old)		
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		
Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	X

Regulation Number 21 CFR 870.2340 **Class*** II (two) **Product Code** 74 DPS

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Linda J. Ricci
2012.11.19 12:20:34 -05'00'  CEMB 11/19/12
(Branch Chief) (Branch Code) (Date)

Final Review:  Owen P. Faris-S
2012.11.19 16:06:19 -05'00' _____
(Division Director) (Date)

Standard Operating Procedures for 510(k) Summaries

- 1) If a 510(k) submitter decides to submit a 510(k) summary, as per 21 CFR 807.87(h), they need to follow the content requirements as per 21 CFR 807.92.
- 2) If during the review of the 510(k), the submitter decides to switch to a 510(k) statement, as per 21 CFR 807.87(h), they may do so while the 510(k) is under review. They must follow 21 CFR 807.93 for a 510(k) statement.
- 3) The 510(k) summary is written by the 510(k) submitter, but FDA will agree with the content prior to clearing any 510(k).
- 4) The 510(k) summary needs to agree with the final classification decision of FDA, e.g., the predicate classification needs to match the FDA classification decision. The submitter may need to revise the summary while the 510(k) is under review. In other words, the 510(k) summary will need to reflect the predicate(s) and decision made by FDA. The submitter will then need to revise the summary while the 510(k) is under review.
- 5) The IFU provided in the 510(k) summary needs to match the IFU statement that is determined to be substantially equivalent
- 6) The 510(k) summary should reflect all the testing done by the 510(k) submitter to demonstrate substantial equivalence. This may include testing that FDA did/would not require to demonstrate substantial equivalence, but would include all testing that FDA does/would require to demonstrate substantial equivalence.
- 7) If the 510(k) summary is deficient, the deficiency(ies) may be put in an AI letter or handled through interactive review.
- 8) The 510(k) may not be found to be substantially equivalent until the 510(k) summary meets the regulatory requirements of 21 CFR 807.92.
- 9) If, after interactions, a 510(k) submitter does not revise the 510(k) summary as requested and we disagree with their rationale, the 510(k) may be found not substantially equivalent for lack of required data/information.
- 10) Neither the 510(k) summary, nor 510(k) statement, are needed if the decision is other than SE.
- 11) The 510(k) summary will go on FDA's website approximately the 5th of the month following any SE decision.

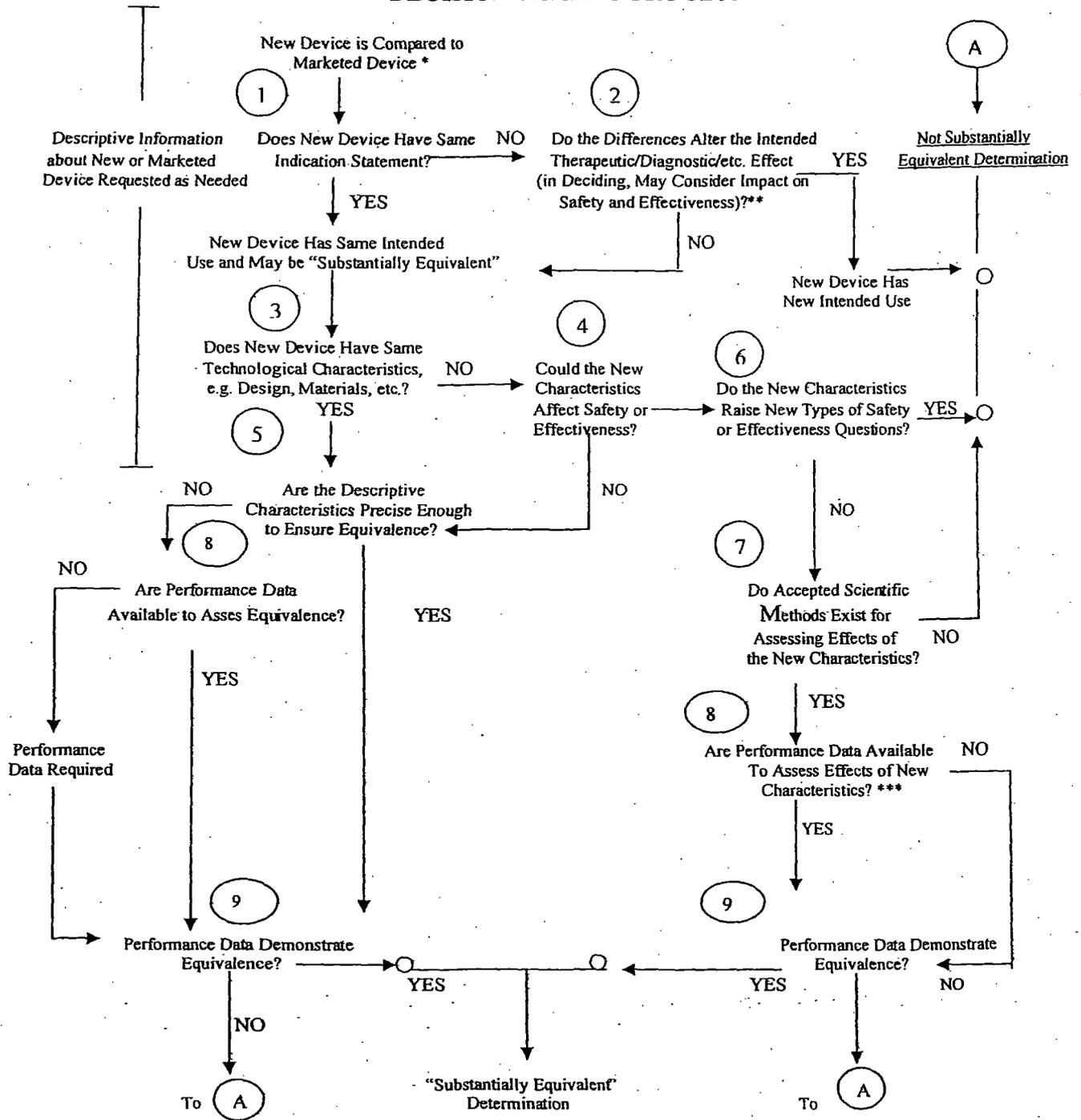
K122356

510(k) SUMMARY REQUIREMENTS CHECKLIST
21 CFR 807.92

All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the	X		

	date the summary was prepared			
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	<u>X</u>		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	<u>X</u>		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	<u>X</u>		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	<u>X</u>		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	<u>X</u>		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence	<u>X</u>		
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)	<u>X</u>		
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.	<u>X</u>		

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K122356/S1

Date: November 14, 2012
To: The Record
From: Frank Lacy, CEMB

Office: ODE
Division: DCD

510(k) Holder: Alivecor, Inc.
Device Name: Alivecor heart monitor for iphone
Contact: Michael Righter
Phone: 415-347-2212
Fax: 415-397-0440
Email: mike@alivecor.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce an electrocardiograph into interstate commerce.

III. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

A standards data report, form FDA-3654, for each of the mentioned recognized consensus standards is provided.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?	X		

The *AliveCor Heart Monitor for iPhone* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. Figure "a" shows the User Interface. The device utilizes the computing power of a Smartphone while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the patient's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor for iPhone* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor for iPhone* uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the *AliveCor Heart Monitor for iPhone Case* (Case), *AliveCor Heart Monitor for iPhone App* (App), and the Apple iPhone 4/4S (iPhone) using iOS 5.1 or later.

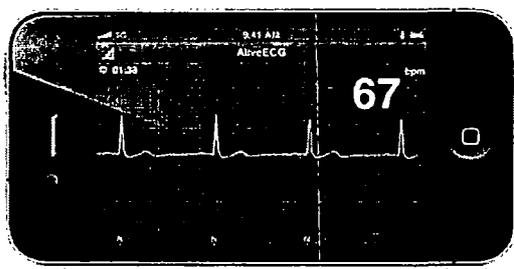


Figure "a": User Interface

The *AliveCor Heart Monitor for iPhone* is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of User (medical professional or patient). In the hands of a medical professional, the *AliveCor Heart Monitor for iPhone* is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional. In the hands of a patient using the device under the prescription of a physician, the *AliveCor Heart Monitor for iPhone* is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional.

The most common method of using the *AliveCor Heart Monitor for iPhone* is to hold the device such that the subjects left and right hands are in contact with the left and right electrodes on the back of the Case, see Figure 1. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the User can experiment to minimize muscle noise and maximize the ECG signal quality. Alternatively, for some subjects, the device may be held up directly to the chest for data acquisition, see Figure 2.

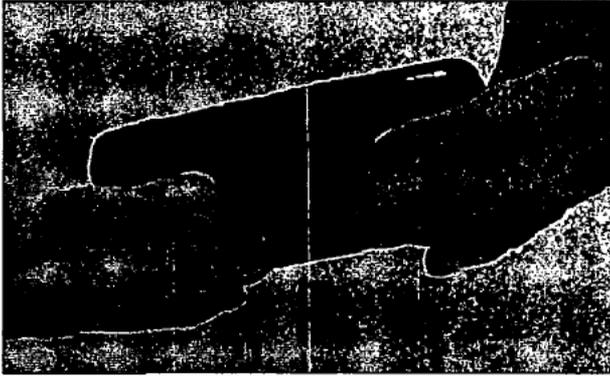


Figure 1: Handheld monitoring

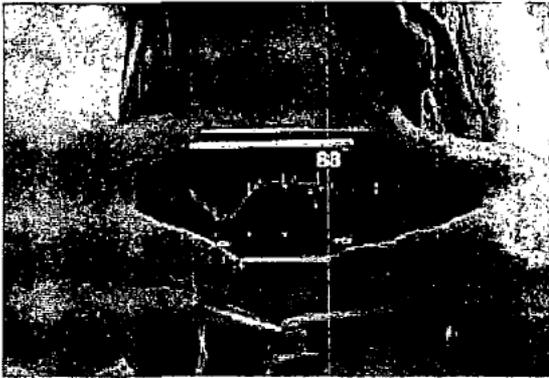


Figure 2: Chest Placement on sternum

In layman's terms, the *AliveCor Heart Monitor for iPhone* wirelessly communicates to the iPhone with human-silent, ultra-low power data transmission protocol. It has extremely accurate front end electronics with high resolution analog-to-digital conversion processed by the iPhone. The iPhone provides the computing horsepower for the App to digitally filter the data and process it to create a high resolution human readable ECG strip.

(b) (4)

Figures 3 and 4 show both sides of the *AliveCor Heart Monitor for iPhone Case*. The "inside" holds the iPhone 4/4S very firmly and provides protection for the front and back glass top layers of the phones from accidental drops onto hard surfaces. The inside of the case also has a battery door with a small Phillips Head screw, which allows changing of the coin cell battery, see Figure 4.

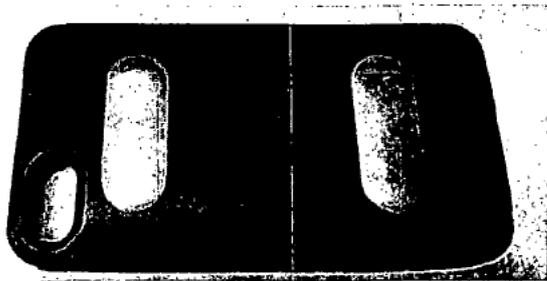


Figure 3: *AliveCor Heart Monitor for iPhone Case*

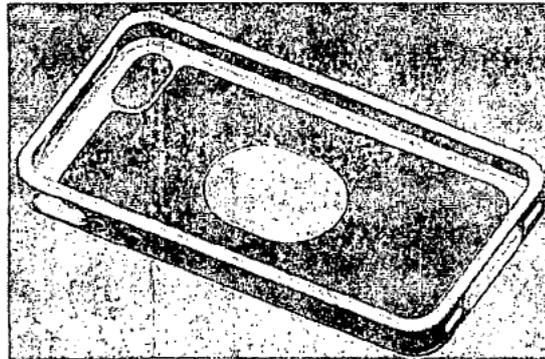


Figure 4: Inner Case (battery cover in yellow)

(b) (4)

II. Indications for Use

According to the manufacturer, the "Indication for Use" states that "The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms."

III. Predicate Device Comparison

The device is said to be Substantially Equivalent to predicate devices:

- * K121009; HeartCheck Pen Handheld Heart Rhythm with GEMS Home; CardioComm Solutions, Inc.

See Comparison Table below

The following comparison table delineates the incremental difference between the approved HeartCheck Pen device and the proposed *AliveCor Heart Monitor for iPhone*. The table includes comparisons of the features and specifications of both devices, including electrical, mechanical,

anatomical, and environmental characteristics. Any differences between the two designs have been marked with bold and discussed after the Comparison Table.

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Indications for Use:</i>	The HeartCheck™ Pen Handheld with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor ECG for iPhone is intended for use by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.
<i>Standards:</i> Essential Performance AECG Safety General Safety EMC Safety	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2
<i>Data Acquisition:</i> Frequency Response ECG channels Resolution Sample Rate	1 Hz – 40Hz Single Channel Unknown 250 Samples/Second	0.5 Hz – 40 Hz Single Channel 16 bit 300 Samples/Second

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Memory Capacity:</i>	20 recordings	Essentially unlimited due to real-time transmission to iPhone memory
<i>Device Classification:</i>	DPS: Electrocardiograph	DPS: Electrocardiograph
<i>Power Supply:</i> Battery	2 AAA batteries	1 Lithium Manganese Dioxide Coin Cells
Battery Life (typical)	Unknown	100 hours operational
<i>User Interface:</i> Primary Lead Data upload Software interface	Lead I, Left to Right Hand USB PC based software	Lead I, Left to Right Hand Ultrasonic transmission iPhone OS based software
<i>Physical Specs:</i> Dimensions, inches Weight	130 x 30 x 20 mm 110 grams	118 x 62 x 16.5 mm 40 grams
<i>Electrodes:</i> Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel
<i>Lead Wires:</i>	None	None
<i>Where used:</i>	Ambulatory outpatient use	Ambulatory outpatient use
<i>Prescribed:</i>	Over-the-Counter	Prescription Only
<i>Environmental:</i> Operating Temp Storage Temp	5 to 40 degrees C -20 to 55 degrees C	10 to 40 degrees C -20 to 60 degrees C

Indications For Use

The modification to the indications for use does not imply a change to the actual indication, but merely clarifies the predicate device indication. Most of the verbiage in the indications for the HeartCheck Pen is in AliveCor's opinion warnings/cautions that should be defined elsewhere as it is defined in our product labeling (See Section 13: Proposed Labeling).

Data Acquisition

The only difference among this group of specifications is that the predicate device has higher bandwidth cutoff at 1 Hz, versus 0.5 Hz for the AliveCor device. The AliveCor device, along with the majority of ambulatory ECG monitors follow the AAMI low-end bandwidth cutoff of 0.5 Hz.

This has proven over the years to be adequate for quality ECG acquisition. The sampling rate of the AliveCor device (300 Hz) is faster than the HeartCheck Pen (250 Hz). Faster sampling can potentially provide finer detail in the ECG rhythm strip, therefore the AliveCor device is substantially equivalent if not better than the predicate.

Memory Capacity

The AliveCor device transmits ECG data in real-time for storage on the iPhone non-volatile flash

memory. Storing data on any handheld device is limited by the size of the on-board memory. The HeartCheck Pen uses onboard memory whereas the AliveCor device utilizes the vast memory capacity of the iPhone. This is essentially the same function, although the AliveCor device transmits to the iPhone before it stores, while the HeartCheck Pen stores before it transmits (via USB) only to store the data again on the PC.

Power Supply

The AliveCor device uses a single coin cell type battery, while the Heart Check Pen uses 2 AAA type batteries. Both of these batteries and battery chemistries are consumer off-the-shelf type batteries. Essentially there is no difference in power type. Lithium coin cell batteries are widely used in a variety of technologies and do not pose any significant safety hazards.

User Interface

The HeartCheck device use a USB cable and PC based software (GEMS Home) to upload, while the AliveCor device uses ultrasonic transmission and the iPhone Operating System. The change from a USB cable to real-time acoustic data transmission is logical for this type of device. For well over 20 years, the industry has been sending acoustic ECGs by means of transtelephonic data transmission (Instromedix, Inc. King of Hearts, iRhythm Technologies, Inc. Event Card, etc.). The AliveCor device is essentially performing the same action, but at an inaudible frequency range that the iPhone 4/4S microphone can receive.

The GEMS Home software package is comparable to the AliveCor Heart Monitor for iPhone mobile application (App). GEMS runs on a PC/Windows based operating system while the App runs on the iPhone Operating System (iOS). The difference in hardware platform (PC versus iPhone) and operating system is not significant as long as the software has been validated for use with the operating system, and those elements of the operating system that are utilized for the software are validated for their particular purpose. AliveCor has a strong software validation protocol for the App, has performed it on the stated versions of hardware (iPhone 4/4S) and the particular validated version of iOS (5.1).

The AliveCor App essentially performs the same actions as GEMS Home to upload ECG Data, store it for future access by a medical professional, and generate clinical quality ECG strip reports. As would a physician view the ECG with GEMS software, they can use the App to view recorded ECG rhythms. A significant advantage to the App compared to GEMS is that you do not have to go to a PC station to upload the data to view it. Additionally, the HeartCheck Pen can display the ECG data in real-time on a small OLED screen, but the AliveCor App allows the ECG to be viewed by a physician directly on the iPhone in real-time or retrospectively on a high resolution display.

Moving the functionality from PC/Windows/software to the iPhone/iOS/App is said to be a logical move to consolidate data handling and transmission. The entire package is in the palm of the user's hand thereby potentially improving efficacy and controlled access to data.

IV. Labeling

Labeling has been reviewed and generally found to be adequate. The Operator's Manuals and Promotional Brochure have been reviewed and found to have labeling that is typical for this ECG. The device is labeled for prescription use only. This is acceptable to this reviewer.

V. Sterilization/Shelf Life/Reuse

The device will be delivered unsterilized to users. The IFU provides instructions for cleaning. These are found to be adequate to this reviewer.

The *AliveCor Heart Monitor for iPhone* is provided non-sterile but assembled and packaged in a clean environment to eliminate particulate contamination. AliveCor's quality system and supplier management system ensure adherence to proper manufacturing conditions for the device. The *AliveCor Heart Monitor for iPhone* has no sterilization requirements.

Additionally, battery testing and analysis was performed and proved that the device has a minimum operating time of 150 hours per the device specifications as defined in the Section 11 – Device Description. There are no critical device functions that deteriorate over time other than the battery life. The battery is a CR2016 coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries. This is acceptable to this reviewer.

VI. Biocompatibility

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the Case or the stainless-steel electrodes.

The biocompatibility assessment for the *AliveCor Heart Monitor for iPhone* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the Case for its utility purpose (as an iPhone case), and using the device for its medical purpose. All testing was performed by a certified laboratory, using ISO-10993 guidelines.

Primarily two components of the Case may contact skin: the Front Case, and more significantly the stainless-steel electrodes.

The Front Case material consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages attached). **(continuous contact)** Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products including a primary use for Smartphone cases.

The electrodes are made from 304SS which is a medical grade stainless-steel. **(continuous contact)** Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

The patient contact components, listed above, have been determined to be biocompatible for skin contact and were tested for cytotoxicity, skin sensitization, and skin irritation with respect to the ISO 10993-1 standard and determined that no additional biocompatibility testing is required. This is acceptable to this reviewer.

VIII. Software

The manufacturer has provided documentation for software development for the software program. They have provided documentation that includes a software description, hazard analysis, software design specifications, validation and verification information, and information about development for a moderate level of concern. It appears that this data is sufficient to assure the safety and effectiveness of the device for the stated moderate level of concern. Also, the manufacturer has provided a comprehensive software analysis that includes a master test plan and result documents, approval test results, product testing

description, and a hazard analysis. The manufacturer has provided information similar to what is contained in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. This reviewer believes that the documentation for the software is adequate and complete.

The manufacturer has provided a Declaration of Conformity to IEC 60601-1-4 (Medical Electrical Equipment, Part 1: General Requirements for Safety, 4. Collateral Standard: Programmable Electrical Medical Systems).

The device does not contain Off The Shelf (OTS) software.

Version: 1.7.2.269		
Level of Concern: Moderate		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

VII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device is said to be tested to comply with the following standards. The manufacturer has supplied declarations of conformities for these standards.

IEC 60601-1; Medical electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-1 Medical Electrical Equipment, Part 1: General Requirements for Safety 1. Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC 60601-1-2 Medical Electrical Equipment, Part 1-2: General Requirements for safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

The above is acceptable to this reviewer.

VIII. Performance Testing – Bench

Laboratory testing was conducted to validate and verify that the subject device meets all design specifications and was substantially equivalent to the predicate devices. The subject device has also been tested to assure compliance to the requirements of various published standards, including IEC 60601-1, IEC60601-1-1 and IEC60601-1-2.

The device has been developed and tested in accordance with ANSI/AAMI EC38-2007 (Ambulatory Electrocardiographs). This is acceptable to this reviewer.

IX. Performance Testing – Animal

N/A

X. Performance Testing – Clinical

See previous review by Dr. Gene Sanders – no concerns

XI. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X
		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?	X	If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: SE

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: need to discuss iOS upgrades and wireless coexistence
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: provide wireless coexistence testing
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XII. Previous Deficiencies and Summary Responses

1. Please address the proprietary applications (APPs) by discussing the minimum recommended hardware and software requirements. Include in your discussion, the potential issue with smartphone OS software is that OS upgrades can render previous applications non-functional (apps that worked on the previous OS do not work with the new OS). Therefore, backward compatibility may be an issue even with minimum requirements.

SUMMARY RESPONSE: adequate; see below

(b) (4)



2. Your 510(k) submission includes a reference to wireless communication. Wireless communication can change the risk profile of the device and thus FDA recommends that you address safety and effectiveness concerns for the use of RF wireless technology in your device. Wireless coexistence is the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules. Wireless coexistence issues are not adequately addressed via the IEC 60601-1-2 standard nor any other current standards. To address these concerns properly the sponsor should define all functions which will be implemented wirelessly, speak to the likelihood of other wireless devices operating in the same vicinity as your device and perform reasonable testing with such devices. In addition, if the sponsor foresees multiple copies of your device to be operated in the same area then this situation should also be included in the testing. A brief summary of the wireless coexistence testing should include the following points:

(b) (4)



(b) (4)



- a. Define all functions to be implemented wirelessly. Describe safeguards and redundancy for the wireless function and possible risks associated with function failure

(b) (4)



(b) (4)

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b. Discuss how the RF antenna could affect other functions of the device.

(b) (4)

A large rectangular area of the document is redacted with a solid grey fill.

c. Detailed information of the RF wireless technology implemented on your device. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for your device. Also include whether other devices (medical or non-medical) can operate on the same network and explain steps chosen to minimize coexistence problems.

(b) (4)

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(b) (4)



- d. Explain all devices to be included in the coexistence test plan and justify their choice and how they represent a worst case scenario. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for all the interfering devices.

(b) (4)



- e. Explain the pass/fail criteria for your device and the interfering devices with justifications on how these criteria were chosen and how they will be quantified and measured. Important parameters to keep in mind while testing are data integrity (ensuring proper function performance) and latency (ensuring functions occur within a timely fashion).

(b) (4)



- f. Explain how the wireless coexistence testing was performed and how the testing addresses the possible risks from other wireless devices. Important parameters are separation distances, number of interferers, location, orientation, etc.

(b) (4)



- g. Proper labeling should be included not only in a user manual, but also on the device itself cautioning users about the risks associated with the use of RF wireless technology and what can be done to mitigate possible interference issues.

(b) (4)



XIII. Contact History

none

XIV. Recommendation

Based on my review, I believe that this device application should be found **Substantially Equivalent (SE)** to predicate devices and I believe that the manufacturer should be notified of our findings.

Regulation Number: 21 CFR 870.2340
 Regulation Name: Electrocardiograph
 Regulatory Class: II (two)
 Product Code: 74 DPS

Reviewer: Frank Lacy	<p>Frank Lacy</p> <small>Digitally signed by Frank Lacy DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Frank Lacy, D 9 2342, 19200300 100 1 1-1300099603 Date: 2012.11.14 13:18:49 -05'00'</small>
Branch Chief	<p>Linda J. Ricci 2012.11.19 11:19:57 -05'00'</p>
Division (if necessary)	

Jones, Ashlee *

From: Microsoft Outlook
o: 'mike@livecor.com'
Sent: Monday, October 22, 2012 3:21 PM
Subject: Relayed: K122356 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'mike@livecor.com' (mike@livecor.com) <mailto:mike@livecor.com>

Subject: K122356 AI Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 22, 2012

ALIVECOR, INC.
SAN FRANCISCO
140 GEARY STREET
SUITE 500
SAN FRANCISCO, CALIFORNIA 94108
ATTN: MICHAEL RIGHTER

510k Number: K122356

Product: ALIVECOR HEART MONITOR FOR IPH

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

122356 / 3001

✓

October 18, 2012

Dear Mr. Lacy,

Attached are the responses to the questions you proposed on September 20th, 2012 regarding our traditional 510(k) submission for the AliveCor Heart Monitor for iPhone (K122356).

This response letter is being sent directly to the Document Mail Center, but in effort to facilitate your review, I have included the response in email form sent on October 18th, 2012.

Sincerely,



MICHAEL RIGHTER
DIRECTOR, REGULATORY AFFAIRS



140 Geary Street, Suite 500

San Francisco, CA 94108

(O) 415.347.2212
(M) 503.544.3295

mike@alivecor.com
www.alivecor.com

FDA CDRH DMC

OCT 22 2012

Received

K17

1. Please address the proprietary applications (APPs) by discussing the minimum recommended hardware and software requirements. Include in your discussion, the potential issue with smartphone OS software is that OS upgrades can render previous applications non-functional (apps that worked on the previous OS do not work with the new OS). Therefore, backward compatibility may be an issue even with minimum requirements.

(b) (4)



(b) (4)



2. Your 510(k) submission includes a reference to wireless communication. Wireless communication can change the risk profile of the device and thus FDA recommends that you address safety and effectiveness concerns for the use of RF wireless technology in your device. Wireless coexistence is the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules. Wireless coexistence issues are not adequately addressed via the IEC 60601-1-2 standard nor any other current standards. To address these concerns properly the sponsor should define all functions which will be implemented wirelessly, speak to the likelihood of other wireless devices operating in the same vicinity as your device and perform reasonable testing with such devices. In addition, if the sponsor foresees multiple copies of your device to be operated in the same area then this situation should also be included in the testing. A brief summary of the wireless coexistence testing should include the following points:

(b) (4)



(b) (4)

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a) Define all functions to be implemented wirelessly. Describe safeguards and redundancy for the wireless function and possible risks associated with function failure.

(b) (4)

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(b) (4)



(b) (4)



(b) (4)



b) Discuss how the RF antenna could affect other functions of the device.

(b) (4)



c) Detailed information of the RF wireless technology implemented on your device. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for your device. Also include whether other devices (medical or non-medical) can operate on the same network and explain steps chosen to minimize coexistence problems.

(b) (4)



(b) (4)



d) Explain all devices to be included in the coexistence test plan and justify their choice and how they represent a worst case scenario. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for all the interfering devices.

(b) (4)



(b) (4)



e) Explain the pass/fail criteria for your device and the interfering devices with justifications on how these criteria were chosen and how they will be quantified and measured. Important parameters to keep in mind while testing are data integrity (ensuring proper function performance) and latency (ensuring functions occur within a timely fashion).

(b) (4)



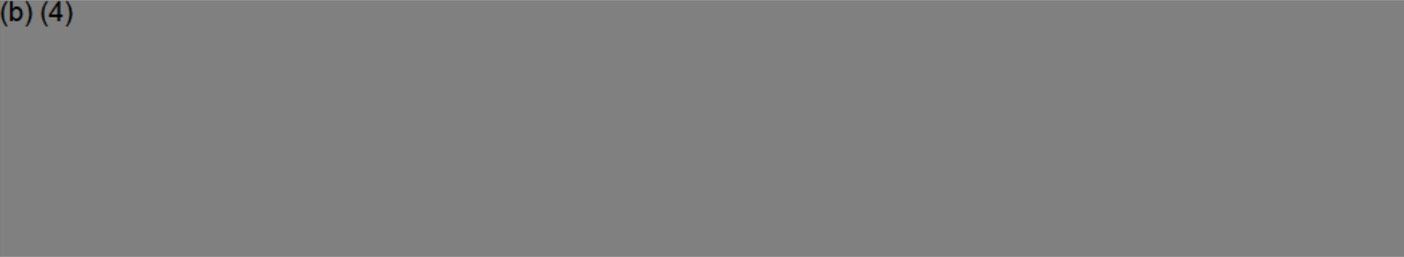
f) Explain how the wireless coexistence testing was performed and how the testing addresses the possible risks from other wireless devices. Important parameters are separation distances, number of interferers, location, orientation, etc.

(b) (4)



g) Proper labeling should be included not only in a user manual, but also on the device itself cautioning users about the risks associated with the use of RF wireless technology and what can be done to mitigate possible interference issues.

(b) (4)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

September 27, 2012

ALIVECOR, INC.
 SAN FRANCISCO
 140 GEARY STREET
 SUITE 500
 SAN FRANCISCO, CALIFORNIA 94108
 ATTN: MICHAEL RIGHTER

510k Number: K122356

Product: ALIVECOR HEART MONITOR FOR IPH

On Hold As of 9/20/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Frank Lacy
Subject: 510(k) Number K122356
To: The Record

Please list CTS decision code TH
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information of Telephone Hold)
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was		<input checked="" type="checkbox"/>	<input type="checkbox"/>

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.



adults

Regulation Number

Class*

Product Code

TH

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief)

(Branch Code)

(Date)

Final Review:

(Division Director)

(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K122356

Date: September 20, 2012
To: The Record
From: Frank Lacy, CEMB

Office: ODE
Division: DCD

510(k) Holder: Alivecor, Inc.
Device Name: Alivecor heart monitor for iphone
Contact: Michael Righter
Phone: 415-347-2212
Fax: 415-397-0440
Email: mike@alivecor.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce an electrocardiograph into interstate commerce.

III. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

A standards data report, form FDA-3654, for each of the mentioned recognized consensus standards is provided.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

The *AliveCor Heart Monitor for iPhone* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. Figure "a" shows the User Interface. The device utilizes the computing power of a Smartphone while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the patient's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor for iPhone* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor for iPhone* uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the *AliveCor Heart Monitor for iPhone Case* (Case), *AliveCor Heart Monitor for iPhone App* (App), and the Apple iPhone 4/4S (iPhone) using iOS 5.1 or later.



Figure "a": User Interface

The *AliveCor Heart Monitor for iPhone* is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of User (medical professional or patient). In the hands of a medical professional, the *AliveCor Heart Monitor for iPhone* is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional. In the hands of a patient using the device under the prescription of a physician, the *AliveCor Heart Monitor for iPhone* is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional.

The most common method of using the *AliveCor Heart Monitor for iPhone* is to hold the device such that the subjects left and right hands are in contact with the left and right electrodes on the back of the Case, see Figure 1. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the User can experiment to minimize muscle noise and maximize the ECG signal quality. Alternatively, for some subjects, the device may be held up directly to the chest for data acquisition, see Figure 2.

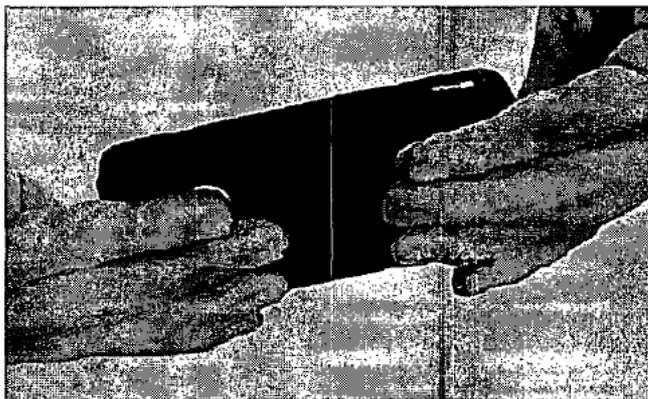


Figure 1: Handheld monitoring

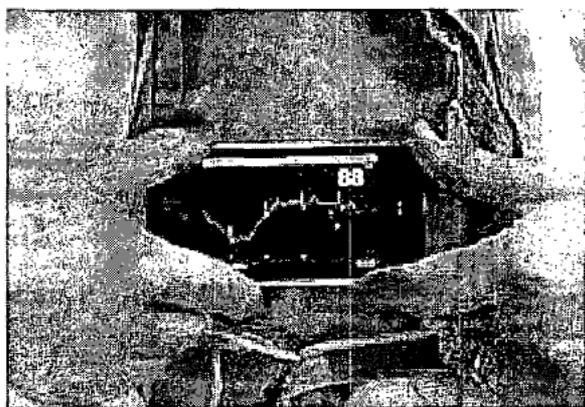


Figure 2: Chest Placement on sternum

In layman's terms, the *AliveCor Heart Monitor for iPhone* wirelessly communicates to the iPhone with human-silent, ultra-low power data transmission protocol. It has extremely accurate front end electronics with high resolution analog-to-digital conversion processed by the iPhone. The iPhone provides the computing horsepower for the App to digitally filter the data and process it to create a high resolution human readable ECG strip.

(b) (4)

Figures 3 and 4 show both sides of the *AliveCor Heart Monitor for iPhone Case*. The "inside" holds the iPhone 4/4S very firmly and provides protection for the front and back glass top layers of the phones from accidental drops onto hard surfaces. The inside of the case also has a battery door with a small Phillips Head screw, which allows changing of the coin cell battery, see Figure 4.

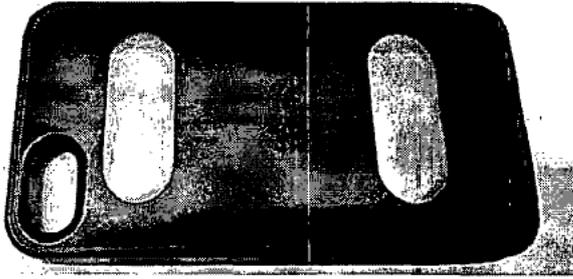


Figure 3: AliveCor Heart Monitor for iPhone Case

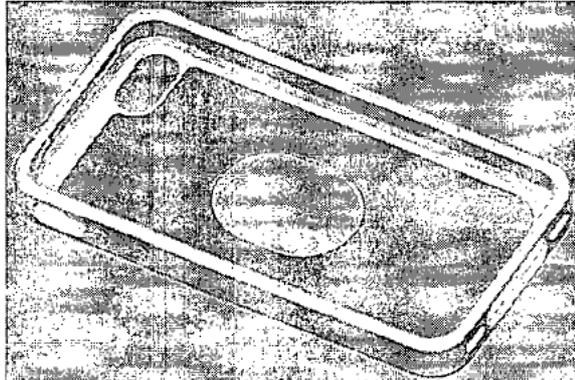


Figure 4: Inner Case (battery cover in yellow)

(b) (4)

II. Indications for Use

According to the manufacturer, the "Indication for Use" states that "The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms."

III. Predicate Device Comparison

The device is said to be Substantially Equivalent to predicate devices:

- * K121009; HeartCheck Pen Handheld Heart Rhythm with GEMS Home; CardioComm Solutions, Inc.

See Comparison Table below

The following comparison table delineates the incremental difference between the approved HeartCheck Pen device and the proposed AliveCor Heart Monitor for iPhone. The table includes comparisons of the features and specifications of both devices, including electrical, mechanical,

anatomical, and environmental characteristics. Any differences between the two designs have been marked with bold and discussed after the Comparison Table.

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Indications for Use:</i>	The HeartCheck™ Pen Handheld with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor ECG for iPhone is intended for use by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.
<i>Standards:</i> Essential Performance AECG Safety General Safety EMC Safety	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2
<i>Data Acquisition:</i> Frequency Response ECG channels Resolution Sample Rate	1 Hz – 40Hz Single Channel Unknown 250 Samples/Second	0.5 Hz – 40 Hz Single Channel 16 bit 300 Samples/Second

Specification	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	AliveCor ECG for iPhone
<i>Memory Capacity:</i>	20 recordings	Essentially unlimited due to real-time transmission to iPhone memory
<i>Device Classification:</i>	DPS: Electrocardiograph	DPS: Electrocardiograph
<i>Power Supply:</i> Battery	2 AAA batteries	1 Lithium Manganese Dioxide Coin Cells
Battery Life (typical)	Unknown	100 hours operational
<i>User Interface:</i> Primary Lead Data upload Software interface	Lead I, Left to Right Hand USB PC based software	Lead I, Left to Right Hand Ultrasonic transmission iPhone OS based software
<i>Physical Specs:</i> Dimensions, inches Weight	130 x 30 x 20 mm 110 grams	118 x 62 x 16.5 mm 40 grams
<i>Electrodes:</i> Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel
<i>Lead Wires:</i>	None	None
<i>Where used:</i>	Ambulatory outpatient use	Ambulatory outpatient use
<i>Prescribed:</i>	Over-the-Counter	Prescription Only
<i>Environmental:</i> Operating Temp Storage Temp	5 to 40 degrees C -20 to 55 degrees C	10 to 40 degrees C -20 to 60 degrees C

Indications For Use

The modification to the indications for use does not imply a change to the actual indication, but merely clarifies the predicate device indication. Most of the verbiage in the indications for the HeartCheck Pen is in AliveCor's opinion warnings/cautions that should be defined elsewhere as it is defined in our product labeling (See Section 13: Proposed Labeling).

Data Acquisition

The only difference among this group of specifications is that the predicate device has higher bandwidth cutoff at 1 Hz, versus 0.5 Hz for the AliveCor device. The AliveCor device, along with the majority of ambulatory ECG monitors follow the AAMI low-end bandwidth cutoff of 0.5 Hz.

This has proven over the years to be adequate for quality ECG acquisition. The sampling rate of the AliveCor device (300 Hz) is faster than the HeartCheck Pen (250 Hz). Faster sampling can potentially provide finer detail in the ECG rhythm strip, therefore the AliveCor device is substantially equivalent if not better than the predicate.

Memory Capacity

The AliveCor device transmits ECG data in real-time for storage on the iPhone non-volatile flash

memory. Storing data on any handheld device is limited by the size of the on-board memory. The HeartCheck Pen uses onboard memory whereas the AliveCor device utilizes the vast memory capacity of the iPhone. This is essentially the same function, although the AliveCor device transmits to the iPhone before it stores, while the HeartCheck Pen stores before it transmits (via USB) only to store the data again on the PC.

Power Supply

The AliveCor device uses a single coin cell type battery, while the Heart Check Pen uses 2 AAA type batteries. Both of these batteries and battery chemistries are consumer off-the-shelf type batteries. Essentially there is no difference in power type. Lithium coin cell batteries are widely used in a variety of technologies and do not pose any significant safety hazards.

User Interface

The HeartCheck device use a USB cable and PC based software (GEMS Home) to upload, while the AliveCor device uses ultrasonic transmission and the iPhone Operating System. The change from a USB cable to real-time acoustic data transmission is logical for this type of device. For well over 20 years, the industry has been sending acoustic ECGs by means of transtelephonic data transmission (Instromedix, Inc. King of Hearts, iRhythm Technologies, Inc. Event Card, etc.). The AliveCor device is essentially performing the same action, but at an inaudible frequency range that the iPhone 4/4S microphone can receive.

The GEMS Home software package is comparable to the AliveCor Heart Monitor for iPhone mobile application (App). GEMS runs on a PC/Windows based operating system while the App runs on the iPhone Operating System (iOS). The difference in hardware platform (PC versus iPhone) and operating system is not significant as long as the software has been validated for use with the operating system, and those elements of the operating system that are utilized for the software are validated for their particular purpose. AliveCor has a strong software validation protocol for the App, has performed it on the stated versions of hardware (iPhone 4/4S) and the particular validated version of iOS (5.1).

The AliveCor App essentially performs the same actions as GEMS Home to upload ECG Data, store it for future access by a medical professional, and generate clinical quality ECG strip reports. As would a physician view the ECG with GEMS software, they can use the App to view recorded ECG rhythms. A significant advantage to the App compared to GEMS is that you do not have to go to a PC station to upload the data to view it. Additionally, the HeartCheck Pen can display the ECG data in real-time on a small OLED screen, but the AliveCor App allows the ECG to be viewed by a physician directly on the iPhone in real-time or retrospectively on a high resolution display.

Moving the functionality from PC/Windows/software to the iPhone/iOS/App is said to be a logical move to consolidate data handling and transmission. The entire package is in the palm of the user's hand thereby potentially improving efficacy and controlled access to data.

IV. Labeling

Labeling has been reviewed and generally found to be adequate. The Operator's Manuals and Promotional Brochure have been reviewed and found to have labeling that is typical for this ECG. The device is labeled for prescription use only. This is acceptable to this reviewer.

V. Sterilization/Shelf Life/Reuse

The device will be delivered unsterilized to users. The IFU provides instructions for cleaning. These are found to be adequate to this reviewer.

The *AliveCor Heart Monitor for iPhone* is provided non-sterile but assembled and packaged in a clean environment to eliminate particulate contamination. AliveCor's quality system and supplier management system ensure adherence to proper manufacturing conditions for the device. The *AliveCor Heart Monitor for iPhone* has no sterilization requirements.

Additionally, battery testing and analysis was performed and proved that the device has a minimum operating time of 150 hours per the device specifications as defined in the Section 11 – Device Description. There are no critical device functions that deteriorate over time other than the battery life. The battery is a CR2016 coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries. This is acceptable to this reviewer.

VI. Biocompatibility

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the Case or the stainless-steel electrodes.

The biocompatibility assessment for the *AliveCor Heart Monitor for iPhone* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the Case for its utility purpose (as an iPhone case), and using the device for its medical purpose. All testing was performed by a certified laboratory, using ISO-10993 guidelines.

Primarily two components of the Case may contact skin: the Front Case, and more significantly the stainless-steel electrodes.

The Front Case material consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages attached). **(continuous contact)**

Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products including a primary use for Smartphone cases.

The electrodes are made from 304SS which is a medical grade stainless-steel. **(continuous contact)** Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

The patient contact components, listed above, have been determined to be biocompatible for skin contact and were tested for cytotoxicity, skin sensitization, and skin irritation with respect to the ISO 10993-1 standard and determined that no additional biocompatibility testing is required. This is acceptable to this reviewer.

VIII. Software

The manufacturer has provided documentation for software development for the software program. They have provided documentation that includes a software description, hazard analysis, software design specifications, validation and verification information, and information about development for a moderate level of concern. It appears that this data is sufficient to assure the safety and effectiveness of the device for the stated moderate level of concern. Also, the manufacturer has provided a comprehensive software analysis that includes a master test plan and result documents, approval test results, product testing

description, and a hazard analysis. The manufacturer has provided information similar to what is contained in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. This reviewer believes that the documentation for the software is adequate and complete.

The manufacturer has provided a Declaration of Conformity to IEC 60601-1-4 (Medical Electrical Equipment, Part 1: General Requirements for Safety, 4. Collateral Standard: Programmable Electrical Medical Systems).

The device does not contain Off The Shelf (OTS) software.

Version: 1.7.2.269		
Level of Concern: Moderate		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

VII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device is said to be tested to comply with the following standards. The manufacturer has supplied declarations of conformities for these standards.

IEC 60601-1; Medical electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-1 Medical Electrical Equipment, Part 1: General Requirements for Safety 1. Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC 60601-1-2 Medical Electrical Equipment, Part 1-2: General Requirements for safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

The above is acceptable to this reviewer.

VIII. Performance Testing – Bench

Laboratory testing was conducted to validate and verify that the subject device meets all design specifications and was substantially equivalent to the predicate devices. The subject device has also been tested to assure compliance to the requirements of various published standards, including IEC 60601-1, IEC60601-1-1 and IEC60601-1-2.

The device has been developed and tested in accordance with ANSI/AAMI EC38-2007 (Ambulatory Electrocardiographs). This is acceptable to this reviewer.

IX. Performance Testing – Animal

N/A

X. Performance Testing – Clinical

See Review by Dr. Gene Sanders

XI. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X
		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?	X	If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: need to discuss iOS upgrades and wireless coexistence
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: provide wireless coexistence testing
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XII. Previous Deficiencies and Summary Responses

1. Please address the proprietary applications (APPs) by discussing the minimum recommended hardware and software requirements. Include in your discussion, the potential issue with smartphone OS software is that OS upgrades can render previous applications non-functional (apps that worked on the previous OS do not work with the new OS). Therefore, backward compatibility may be an issue even with minimum requirements.
2. Your 510(k) submission includes a reference to wireless communication. Wireless communication can change the risk profile of the device and thus FDA recommends that you address safety and effectiveness concerns for the use of RF wireless technology in your device. Wireless coexistence is the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules. Wireless coexistence issues are not adequately addressed via the IEC 60601-1-2 standard nor any other current standards. To address these concerns properly the sponsor should define all functions which will be implemented wirelessly, speak to the likelihood of other wireless devices operating in the same vicinity as your device and perform reasonable testing with such devices. In addition, if the sponsor foresees multiple copies of your device to be operated in the same area then this situation should also be included in the testing. A brief summary of the wireless coexistence testing should include the following points:
 - a. Define all functions to be implemented wirelessly. Describe safeguards and redundancy for the wireless function and possible risks associated with function failure.
 - b. Discuss how the RF antenna could affect other functions of the device.
 - c. Detailed information of the RF wireless technology implemented on your device. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for your device. Also include whether other devices (medical or non-medical) can operate on the same network and explain steps chosen to minimize coexistence problems.
 - d. Explain all devices to be included in the coexistence test plan and justify their choice and how they represent a worst case scenario. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for all the interfering devices.
 - e. Explain the pass/fail criteria for your device and the interfering devices with justifications on how these criteria were chosen and how they will be quantified and measured. Important parameters to keep in mind while testing are data integrity (ensuring proper function performance) and latency (ensuring functions occur within a timely fashion).
 - f. Explain how the wireless coexistence testing was performed and how the testing addresses the possible risks from other wireless devices. Important parameters are separation distances, number of interferers, location, orientation, etc.

- g. Proper labeling should be included not only in a user manual, but also on the device itself cautioning users about the risks associated with the use of RF wireless technology and what can be done to mitigate possible interference issues.

XIII. Contact History

none

XIV. Recommendation

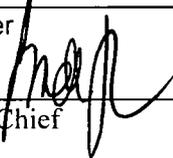
Based on my review, I believe that this device application should be placed on **Telephone Hold (TH)** and I believe that the manufacturer should be notified of our findings.

Regulation Number: 21 CFR 870.2340

Regulation Name: Electrocardiograph

Regulatory Class: II (two)

Product Code: 74-DPS

Reviewer 
Branch Chief 

9/20/12
Date
9/20/12
Date

**OFFICE OF DEVICE EVALUATION
510(k) CLINICAL REVIEW**

From: William E. Sanders, Jr. MD MBA FHRS FACC
CEMB, DCD, ODE

To: Frank Lacy
CEMB, DCD, ODE

CC: Felipe Aguel, Ph.D., CEMB Branch Chief

File: K122356

Device: AliveCor Heart Monitor for iPhone

Sponsor: AliveCor, Inc.

Date: September 6, 2012

RECOMMENDATION:

Approval

SUMMARY:

This document is a sponsor submitted 510(k) (K122356) which proposes use of the AliveCor Heart Monitor for iPhone for the purpose of recording the lead I tracing of an electrocardiogram (ECG) and transmitting that recording to a server where it is available for review and analysis. This single-channel ECG acquisition device permits display and transmission of a tracing that provides a medical professional (*e.g.* physician, nurse, EMT) with information similar to that of an event recorder. The device automatically records the data on the smartphone and the associated smartphone application uploads the data with minimal patient interaction.

The sponsor, AliveCor Inc., has submitted data from two trials, the first evaluating the validity of the ECG tracing compared to the GE MAC5500 (a standard ECG machine) and the second assessing the “casual use” of this device by subjects. These prospective, un-blinded, non-randomized trials are intended to provide the clinical support for this 510(k) application. I have reviewed the studies, which are yet to be published in a peer reviewed fashion, as well as the “User Manual.” These trials were conducted at excellent centers by very experienced physicians (electrophysiologists in both cases). There appears to be low risk in obtaining this type of ECG

K122356
AliveCor-iPhone

data and significant potential benefit in the utilization of such information for both the patient and physician. I do not feel any further clinical data is necessary and would recommend approval.

BACKGROUND INFORMATION

Brief Device Description and History (Device Description Document-Section 11, pages 1-2)

“The AliveCor Heart Monitor for iPhone (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the computing power of a Smartphone while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the patient’s hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the AliveCor Heart Monitor for iPhone uses a proprietary method of data transmission using acoustic waves. The AliveCor Heart Monitor uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the AliveCor Heart Monitor for iPhone Case (Case), AliveCor Heart Monitor for iPhone App (App), and the Apple iPhone 4/4S (iPhone) using iOS 5.1 or later.”

“The AliveCor Heart Monitor for iPhone is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of User (medical professional or patient). In the hands of a medical professional, the AliveCor Heart Monitor for iPhone is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional.

In the hands of a patient using the device under the prescription of a physician, the AliveCor Heart Monitor for iPhone is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional.

The most common method of using the AliveCor Heart Monitor for iPhone is to hold the device such that the subjects left and right hands are in contact with the left and right electrodes on the back of the Case, see Figure 3. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the User can experiment to minimize muscle noise and maximize the ECG signal quality. Alternatively, for some subjects, the device may be held up directly to the chest for data acquisition.”

K122356
AliveCor-iPhone

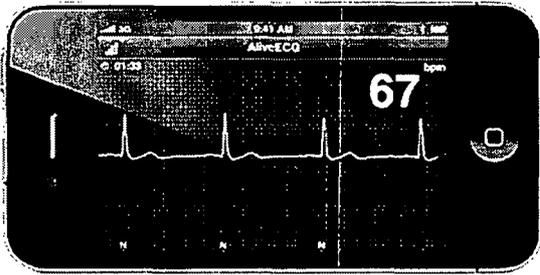


Figure 1: User Interface



Figure 2: AliveCor Heart Monitor for iPhone Case

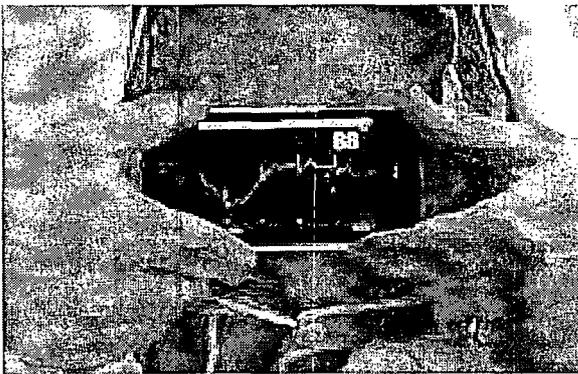


Figure 3: Handheld monitoring



Figure 4: Chest Placement on sternum

“There are just two modes of operation for the Case, STANDBY and ON. In the STANDBY mode, the electronic circuitry is actively looking for a connection between the electrodes (impedance). When the Case detects presence of a conductive path between the electrodes (hands or skin contact), it turns ON and begins to emanate a modulated ultrasonic frequency (inaudible pressure wave) with a piezo oscillator, see Figure 6. After the electrodes are removed from the conductive path, the Case returns to the STANDBY mode.”

Intended Use of Device (Device Description Document-Section 11, pages 1)

The AliveCor Heart Monitor for iPhone is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip.

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Indications for Use (Indications for Use Statement-Section 4, page 1 and Executive Summary-Section 10, page 1)

“The AliveCor Heart Monitor for iPhone is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.”

“The device is issued via prescription only, and should be used in accordance with the instructions as indicated in the User Manual and as directed by a physician.”

Reviewer's Comment: The indications for use are satisfactory.

Clinical Background

Traditionally loop or event recorders have been employed as diagnostic tools to evaluate patients with recurrent symptoms of tachyarrhythmia but no documented rhythm abnormality. They are physician prescribed devices that record on patient demand. The data (an ECG single lead strip) is then manually transfer by the patient, via phone or more recently computer, to his or her physician for evaluation.

SUMMARY OF PRIOR INVESTIGATIONS

(b) (4)



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(b) (4)

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Reviewer's Comment on Validation Trial:

(b) (4)

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(Performance Testing-Clinical, Section 20, page 12)

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(b) (4)



The Conclusions included the following:

(b) (4)



(Performance Testing-Clinical, Section 20, page 13)

(b) (4)



Reviewer's Comments on Subject Trial:

(b) (4)



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(b) (4)



Labeling

The “User Manual” and “Quick Start Guide” were included in Section 13, pages 1-18-Proposed Labeling. I have reviewed both.

Reviewer’s Comments

(b) (4)



REVIEW CONCLUSIONS/RECOMMENDATION

(b) (4)



REFERENCES

(b) (4)



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