CARDIOLOGIC®
SYSTEMS, INC.

September 11, 1998

2612 '98 SEP 14 A10:59

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

RE: **IDE Number G960214/21**
CardioLogic VEST-CPR® System
Public Disclosure After Study Termination

Dear Sir/Madam:

In accordance with Federal Regulation 21 CFR §50.24 (a) (7) (ii) and (iii), §56.109(g) and §812.47(a), we are submitting public disclosure information that appraised the community and researchers of the termination of the VEST-CPR study and its results.

As required by Federal Regulation 21 CFR §56.109(g) and §812.47(a), each IRB has provided a copy of the information that was publicly disclosed. In addition, the IRB's have provided written verification of their review and approval of the information prior to its disclosure.

A duplicate copy of this information has been sent to Dockets Management at the following address:

Docket number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive Room 1-23
Rockville, MD 20857

I would appreciate the FDA considering IDE G960214 officially terminated and all requirements completed in accordance with Federal Regulation 21 CFR §812.150 (7).

If you have any questions, please do not hesitate to contact me at (410) 691-5200.

Sincerely,

Linda Gregg
Director of Clinical Affairs
Official Correspondent

95S-0158

RPT 4

CARDIOLOGIC SYSTEMS, INC., 7455-T NEW RIDGE ROAD, HANOVER, MD 21076-3143 U.S.A. • TEL 410.691.5200 • FAX 410.691.5212

CARDIOLOGIC SYSTEMS, INC.

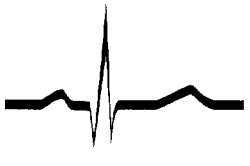
INVESTIGATIONAL DEVICE EXEMPTION
NUMBER G960214

SUPPLEMENT # 21

September 11, 1998

Volume 1 of 1

Sponsored By:
CardioLogic Systems, Inc.
7455-T New Ridge Road
Hanover, Maryland, USA 21076-3143



CARDIOLOGIC®
SYSTEMS, INC.

2613 '98 SEP 14 A10:59

INVESTIGATIONAL DEVICE EXEMPTION NUMBER G960214
SUPPLEMENT # 21

VEST-CPR SYSTEM

Public Disclosure and Community Notification Regarding Study Termination

Submittal Date: September 11, 1998

Sponsored By:

CardioLogic Systems, Inc.
7455-T new Ridge Road
Hanover, Maryland, USA 21076

(Tel) 410-691-5200
(Fax) 410-691-5212

CardioLogic Systems, Inc.

Investigational Device Exemption Number G960214/S21

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Hamot

Hamot Research Center
104 East 2nd Street
Erie, PA 16507
(814) 877-6026
Fax: (814) 877-5089

Linda Gregg
Cardiologic Systems, Inc.
7455-T New Ridge Rd.
Hanover, MD 21076-3143

June 2, 1998

Dear Ms. Gregg,

On May 21, 1998, Geoffrey Burbridge, MD, Chairman of the Hamot Medical Center Institutional Review Committee provided expedited review and approval of a community notification disclosure for the study, "Clinical investigation of the VEST-CPR system in Adults". When this approval was reported at the June 1, 1998 IRC meeting, suggestions were made to revise the advertisement (Attachment 1).

Would you please revise the community notification disclosure as specified and return for review by our Community Relations and Risk Management Departments. Thank you for your assistance.

Sincerely,

Phyllis J. Kuhn

Phyllis J. Kuhn, PhD
IRC Secretary

HAMOT MEDICAL CENTER

VEST-CPR® STUDY

COMMUNITY NOTIFICATION

Though Hamot did not enroll any patients,

Hamot Medical Center of Erie, Pennsylvania was one of four centers in the United States that was chosen to participate in a study of a new, potentially life-saving treatment for patients suffering cardiac arrest. Randomly selected patients suffering cardiac arrest ~~in selected areas of the hospital~~ at the other were treated with a new way of performing Cardio-Pulmonary Resuscitation (CPR). The conditions of the study were carefully described in an FDA-approved Investigational Device Exemption.

The new treatment, called VEST-CPR, relied on a device invented at The Johns Hopkins University Hospital in Baltimore and developed by CardioLogic Systems, Inc., located in Hanover, Maryland. This device performed the CPR chest compressions using a "vest", resembling an oversized blood pressure cuff, around the chest. Scientific evidence indicated that VEST-CPR may increase the survival rate of cardiac arrest patients over manual CPR.

~~Ten (10) patients were enrolled into the study~~ from 28-Jul-97 to 29-Oct-97. Three (3) patients received manual CPR, while the remaining seven (7) patients received VEST-CPR. Of the three manual patients, ~~only~~ one (1) experienced a return of a spontaneous circulation. This patient eventually rearrested and did not survive. Of the seven (7) vest patients, three (3) experienced a return of a spontaneous circulation. These three patients did not survive after rearresting in the hospital.

Nationwide men from 7/28/97 to 10/29/97
Seven (7) ~~males~~ and three (3) ~~females~~ women were enrolled. The average age was 72.3 years. The average duration of CPR was 13.80 minutes (manual = 14.67, vest = 13.43). The primary diagnosis, or arrest causality, was myocardial infarction (4), congestive heart failure (4), lethal arrhythmias (1), and end-stage leukemia (1).

An exception from consent, authorized by the U.S. Food and Drug Administration (21 CFR 50.24), was used for all ~~10~~ 7 patients, as ~~It was not feasible to obtain~~ obtaining informed consent from the patient, a family member, or a legally authorized representative at the time ~~when~~ the patient was in critical need for immediate treatment, was not feasible.

because of lack of funding.

On November 7, 1997 CardioLogic suspended and then terminated all investigations of the VEST-CPR system. If you have any questions about the study, you may contact Linda Gregg, Director of Clinical Affairs, CardioLogic Systems, Inc., 1-800-321-4277.

RECEIVED MAY 1 2 1998

NO HAMOT MEDICAL CENTER PATIENTS WERE TREATED WITH THE

Hamot

Hamot Medical Center
201 State Street
Erie, PA 16550
(814) 877-6000
http://www.hamot.org

Linda Gregg
Cardiologic Systems, Inc.
7455-T New Ridge Rd.
Hanover, MD 21076-3143

May 21, 1998

Dear Ms. Gregg:

On May 21, 1998, a community notification disclosure for the study, "Clinical investigation of the VEST-CPR system in Adults", was approved through expedited review. This disclosure received previous review and approval from representatives of the Food and Drug Administration.

Sincerely,

Geoffrey R Burbridge MD

Geoffrey Burbridge, MD, IRC Chairman

cc. Leo Bennett, MD
Brad Cooper, PharmD
Phyllis J. Kuhn, PhD, IRC Secretary

HAMOT MEDICAL CENTER
VEST-CPR® STUDY
COMMUNITY NOTIFICATION

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HAMOT MEDICAL CENTER
VEST-CPR® STUDY
COMMUNITY NOTIFICATION

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Presbyterian Healthcare System

Presbyterian Hospital
200 Hawthorne Lane
Post Office Box 33549
Charlotte, NC 28233-3549
(704) 384-4000
http://www.presbyterian.org

July 12, 1998

Amicus Research
Presbyterian Healthcare
200 Hawthorne Lane
Charlotte NC 28207

RE: IRB # 97009 - CPR Vest Trial

This is to confirm for your records that the revision for the above referenced protocol was approved by the Institutional Review Board (IRB) on July 12, 1998 through expedited review and four other IRB voting members.

Revision includes a public notification article regarding the completion of the aforementioned study and the outcome.

A copy of this revision is on file in the IRB Office. Any changes must be submitted to the IRB for approval prior to implementation. Any unexpected or significant adverse events should be reported immediately.

The Institutional Review Board is in compliance with the requirements in Part 56, Subchapter D, Part 312 of 21 Code of Federal Regulations.

Robert Farnham, MD, Chairperson
Institutional Review Board

AMICUS RESEARCH FOUNDATION/MID CAROLINA CARDIOLOGY
PRESBYTERIAN HOSPITAL
VEST-CPR® STUDY
COMMUNITY NOTIFICATION

Presbyterian Hospital of Charlotte, NC was one of four centers in the United States chosen to participate in a study of a new, potentially life-saving treatment for patients suffering cardiac arrest. Randomly selected patients suffering cardiac arrest in selected areas of the hospital were treated with a new way of performing Cardio-Pulmonary Resuscitation (CPR). The conditions of the study were carefully described in an FDA approved Investigational Device Exemption.

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Unfortunately, just shortly after the study began, on November 7, 1997 CardioLogic suspended and then terminated all investigations of the VEST-CPR system in order to pursue other company interests. Nationally, only ten (10) patients were enrolled into the study from 28-Jul-97 to 29-Oct-97. Seven (7) males and three (3) females were enrolled. The average age was 72.3 years while the average duration of CPR was 13.80 minutes. Three (3) patients received manual CPR while the remaining seven (7) patients received VEST-CPR. Of the three manual patients, only one (1) experienced a return of a spontaneous circulation. This patient eventually rearrested and did not survive. Of the seven (7) vest patients, three (3) experienced a return of a spontaneous circulation. These three patients did not survive after rearresting in the hospital.

The need to find a better resuscitation technique is indisputable. Studies have shown that when a patient fails initial defibrillation, even the best manual CPR results in a long term survival rate of only 5-10%. It is unfortunate that the question of whether VEST-CPR is any better than standard CPR will have to await further study.

If you have any questions about the study, you may contact Linda Gregg, Director of Clinical Affairs, CardioLogic Systems, Inc., 1-800-321-4277.

P2788490

THE CHARLOTTE OBSERVER

20C WEDNESDAY, JULY 22, 1998 • • •

AMICUS RESEARCH FOUNDATION/MID CAROLINA CARDIOLOGY
PRESBYTERIAN HOSPITAL
VEST-CPR® STUDY
COMMUNITY NOTIFICATION

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P2788490

VCU
MCV Campus

Virginia Commonwealth University

Department of Oral and Maxillofacial Surgery

School of Dentistry
521 North 11th Street
P.O. Box 980566
Richmond, Virginia 23298-0566

804 828-0602
FAX: 804 828-0056
TDD: 1-800 828-1120

Daniel M. Laskin, DDS, MS
Professor and Chairman

Robert L. Campbell, DDS
Professor

James A. Giglio, DDS, M.Ed.
Associate Professor

Robert A. Strauss, DDS
Associate Professor

A. Omar Abubaker, DMD, Ph.D.
Associate Professor

May 12, 1998

Ms. Linda Gregg
Cardiologic Systems, Inc.
7455-T New Ridge Road
Hanover, Maryland 21076-3134

Dear Ms. Gregg:

This letter is to confirm that I reviewed and approved the Community Notification regarding the termination of the VEST-CPR clinical trial.

Thank you,

Robert L. Campbell, D.D.S.
Professor
Oral and Maxillofacial Surgery
and Anesthesiology

RLC:rth

VIRGINIA

B4 SATURDAY, JULY 25, 1998 • RICHMOND TIMES-DISPATCH

VIRGINIA COMMONWEALTH UNIVERSITY AND MEDICAL COLLEGE OF VIRGINIA HOSPITALS VEST-CPR® STUDY COMMUNITY NOTIFICATION

The Virginia Commonwealth University and Medical College of Virginia Hospitals were one of four centers in the United States chosen to participate in a study of a new, potentially life-saving treatment for patients suffering cardiac arrest. Randomly selected patients suffering cardiac arrest in selected areas of the hospital were treated with a new way of performing Cardio-Pulmonary Resuscitation (CPR). The conditions of the study were carefully described in an FDA approved Investigational Device Exemption.

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The need to find a better resuscitation technique is indisputable. Studies have shown that when a patient fails initial defibrillation, even the best manual CPR results in a long term survival rate of only 5-10%.

If you have any questions about the study, you may contact Linda Gregg, Director of Clinical Affairs, CardioLogic Systems, Inc., 1-800-321-4277.

VIRGINIA

B4 TUESDAY, JULY 21, 1998 • RICHMOND TIMES-DISPATCH

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Glendale News-Press
WEDNESDAY, SEPTEMBER 2, 1998 25 CENTS
erving the Glendale community since 1905

GLENDALE MEMORIAL HOSPITAL AND HEALTH CENTER VEST-CPR® STUDY COMMUNITY NOTIFICATION

The Glendale Memorial Hospital and Health Center was one of four centers in the United States chosen to participate in a study of a new, potentially life-saving treatment for patients suffering cardiac arrest. Randomly selected patients suffering cardiac arrest in selected areas of the hospital were treated with a new way of performing Cardio-Pulmonary Resuscitation (CPR). The conditions of the study were carefully described in an FDA approved Investigational Device Exemption.

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LINDA - I think this is probably OK too much data - but that is what is required so OK. TX Don Gunning

GLENDALE MEMORIAL HOSPITAL AND HEALTH CENTER
VEST-CPR® STUDY
COMMUNITY NOTIFICATION

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SPH31

FedEx® USA Airbill

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0200 Form I.D. No.

Recipient's Copy

1 From

Date 11-SEP-98

Sender's Name LINDA [illegible] Phone (410) 691-5200

Company CARDIOLOGIC SYS INC

Address 7455 NEW RIDGE RD STE T

Dept./Floor/Suite/Room

City HANOVER State MD ZIP 21076

2 Your Internal Billing Reference Information

3 To

Recipient's Name DOCKET ANNEX 155-1150 Phone (301) 443-[illegible]

Company DOCKETS MANAGEMENT BRANCH (HFA-305)-FDA

Address 12420 PARKLAWN DR. ROOM 1-23

Check here if residence (Extra charge applies for FedEx Express Saver)

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City ROCKVILLE State MD ZIP 20857

For HOLD at FedEx Location check here

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For Saturday Delivery check here

☐ (Extra Charge. Not available to all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

8 0 0 1 2 9 5 2 4 1 0 8

4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas.

☐ FedEx Priority Overnight (Next business morning)

☒ FedEx Standard Overnight (Next business afternoon)

☐ FedEx 2Day* (Second business day)

☐ FedEx Express Saver* (Third business day)

☐ FedEx First Overnight (Earliest next business morning delivery to select locations) **(Higher rates apply)**

* FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

☐ FedEx Overnight Freight (Next business day)

☐ FedEx 2Day Freight (Second business day)

☐ FedEx Express Saver Freight (Up to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging

☐ FedEx Letter ☐ FedEx Pak (Declared value limit $500.) ☒ FedEx Box ☐ FedEx Tube ☐ Other Pkg.

6 Special Handling

Does this shipment contain dangerous goods? ☐ Yes (As per attached Shipper's Declaration) ☐ Yes (Shipper's Declaration not required)

☐ Dry Ice Dry Ice, 9, UN 1845 III ____ x ____ kg. 904 (Dangerous Goods Shipper's Declaration not required)

CA ☐ Cargo Aircraft Only

7 Payment

Bill to: ☒ Sender (Account no. in section 1 will be billed) ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check ☐ Obtain Recipient FedEx Account No.

(Enter FedEx account no. or Credit Card no. below)

Total Packages	Total Weight	Total Declared Value*	Total Charges
1	1	$ .00	$

* When declaring a value higher than $100 per shipment, you pay an additional charge. See **SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY** section for further information.

Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims

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Questions?
Call 1·800·Go·FedEx (800)463-3339

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