

K030535



JUN 11 2003

**510(k) SUMMARY
of
SAFETY and EFFECTIVENESS**

A. General Information

1. *Submitter's Name:* QRS Diagnostic, LLC
2. *Address:* 14755 27th Avenue No.
Plymouth, MN 55447
3. *Telephone:* 763-559-8492, Ext. 952
4. *Contact Person:* Brad Sorenson
5. *Date Prepared:* December 17, 2002
6. *Registration Number:* 2133542

B. Device

1. *Name:* EKGCARD™ System
2. *Trade Name:* EKGCARD™ System
3. *Common Name:* Diagnostic Electrocardiograph
4. *Classification Name:* Electrocardiograph (ECG or EKG)
5. *Product Code:* DPS
6. *Class:* II
7. *Regulation Number:* 870.2340

C. Identification of Legally Marketed Devices

1. *Name:* Biolog 3000 and ECG Interface
2. *K Number:* K974351 and K974220
3. *Date Cleared:* April 1, 1998 and August 25, 1998

D. Description of the Device

The EKGCARD™ System is a diagnostic electrocardiograph (ECG or EKG) for 12 channel resting ECG's. The patient population is for both male and female, pediatric and adult. The system has been tested to the following standards:

- IEC 601-1, 60601-1; 1991
- IEC 601-2-25; 1993
- ANSI/AAMI EC11 – 1991
- ANSI/AAMI EC53 – 1995
- ANSI/AAMI ES1 – 1993
- CUL 601-1
- UL 2601-1
- EN60601-1-2
- EN 55011
- EN 61000-4-2
- EN 61000-4-3
- EN 61000-4-4
- EN-61000-4-6
- EN-61000-4-8
- ISO 10993
- 21CFR Part 898
- 21CFR Part 801
- 93/42/EEC
- EN 980
- 21CFR Part820

The EKGCARD™ System is an electrocardiograph that detects signals associated with cardiac activity and produces an ECG; a graphical record of the voltage versus time. ECG's are routinely used to diagnose cardiac abnormalities, determine a patient's response to drug therapy, and reveal trends of changes in heart function.

The System requires a Type II PC Card Slot and Windows CE Pocket PC 2002 and is a Prescription Device.

E. Intended Use Statement

Diagnostic ECG for 12 Channel Resting ECG
Patient Population: Male/Female, Pediatric to Adult
Environment of Use: Hospital, Clinic and Home Use

F. Components/ Part Numbers

- User's Manual 6000-4332
- EKGCard 7000-1000 WLD
- ECG Cable 2010-3722 (IEC)
- ECG Cable 2010-3721 (AAMI)
- Snap Adapters 5000-1861
- Tab Adapters 5000-1858
- Snap Electrodes 5000-1859
- Tab Electrodes 5000-1858

G. Table of Comparisons

The following summary tables of comparisons compare the new device (EKGCard System) to the predicate devices: Biolog 3000 and ECG Interface.

#	Area	New Device: EKGCard™ System	Predicate Device: Biolog 3000 or ECG Interface	Same	Different
1	Indications for Use	ECG and Connection to Pocket PC	ECG and Connection to Pocket PC	X	
2	Patient Population	Male/Female Pediatric to Adult	Male/Female Pediatric to Adult	X	
3	Environment	Hospital, Clinic, Home Use	Hospital, Clinic, Home Use	X	
4	Number of Electrodes	12 Lead ECG	12 Lead ECG	X	
5	Batteries	No	No	X	
6	Internal Isolation	Yes	Yes	X	
7	Defibrillator Protection	Yes	Yes	X	
8	Banana Plugs	Yes	Yes	X	
9	Types of Electrodes	Snap or Tab	Snap or Tab	X	
10	CMRR	Yes	Yes	X	
11	Heart Rate	Yes	Yes	X	

12	Standards AAMI, EC11	Yes	Yes	X	
13	Standards 60601-2-25	Yes	Yes	X	
14	Interpretation	No	Yes		X
15	Transtelephonic	No	Yes		X
16	Cable Length 3 Feet, 5 Feet	Yes	Yes	X	
17	Type BF	Yes	Yes	X	
18	Filters	50 or 60 Hz	50 or 60 Hz	X	
19	Connection Status	Yes	Yes	X	
20	Electrode Labeling	IEC or AAMI	IEC or AAMI	X	
21	Print EKG's	No	Yes		X
22	Supplied Non-Sterile	Yes	Yes	X	
23	Prescription Device	Yes	Yes	X	
24	Safety Standards	Yes	Yes	X	
25	EMC Standards	Yes	Yes	X	
26	Operating Conditions	Yes	Yes	X	

H. Discussion of Similarities and Differences

The EKGCard and Biolog 3000 or ECG Interface have the following similarities:

- Indications for Use
- Patient Population
- Environment Number of Electrodes
- Batteries
- Internal Isolation
- Defibrillator Protection
- Banana Plugs
- Types of Electrodes
- CMRR
- Heart Rate
- Standards – EC11
- IEC 60601-2-25

- Cable Length
- Type BF
- Filters
- Connection Status
- Electrode Labeling
- Non-Sterile
- Prescription Device
- Safety
- EMC
- Operating Conditions

The differences, with comments, are the following:

- Interpretation – The EKGCARD does not have interpretation, whereas the Biolog 3000 does or can.
- Transtelephonic – The EKGCARD does not have the capability to transmit ECG's trans-telephonically.
- Print ECG – The EKGCARD does not yet have the ability to print EKG's.

The above differences do not raise any new types of safety or effectiveness questions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

QRS Diagnostics, LLC
c/o Mr. Alan Barker
British Standards Institution
Maylands Avenue
Hemel Hempstead
Hertfordshire, HP2 4SQ
United Kingdom

Re: K030535
Trade Name: EKGCARD™
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: Undated
Received: May 27, 2003

Dear Mr. Barker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

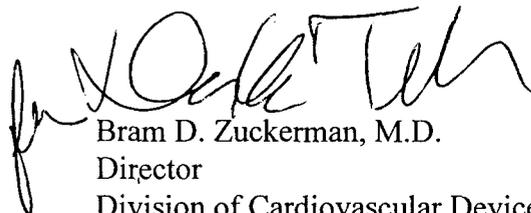
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Alan Barker

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B" and "Z".

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

Enclosure

K030535

510(k) Number: *To be determined*

Device Name: EKGCard™ System

Indications for Use:

- Diagnostic ECG for 12 Channel Resting ECG
 - Patient Population: Male/Female/Pediatric to Adult
 - Environment of Use: Hospital, Clinic, and Home Use
 - Prescription Device by a Physician

PLEASE DO NOT WRITE BELOW THIS LINE –
 CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR OVER-THE-COUNTER USE
 (optional Form 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030535