K031964

SEP - 5 2003

510(K) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. *Submitter's Name:*	QRS Diagnostic, LLC
2. *Address:*	14755 27th Avenue North Plymouth, MN 55447
3. *Telephone:*	763-559-8492, Ext. 958
4. *Contact Person:*	Mary Kay Jensen
5. *Date Prepared:*	June 21, 2003
6. *Registration Number:*	2133542

B. Device

1. *Name:*	BPCard™
2. *Trade Name:*	BPCard
3. *Common Name:*	Blood Pressure Monitor
4. *Classification Name:*	Non-Invasive Blood Pressure Measurement System
5. *Product Code:*	DXN
6. *Class:*	II
7. *Regulation Number:*	870.1130

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www.QRSdiagnostic.com

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C. Identification of Legally Marketed Devices

1. *Name:* Accutracker DX
2. *K Number:* K913844
3. *Date Cleared:* July 14, 1992

D. Description of the Device

The BPCard™ is a non-invasive Blood Pressure Monitor. The patient population is for both male and female, pediatric and adult. The BP Card has been tested to the following standards:

- AAMI SP10-1992-Electronic or Automated Sphygmomanometers
- FDA-1997-NIBP Monitor Guidance
- EN1060-1-Non-Invasive Sphygmomanometers General Requirements
- EN1060-3-Non-Invasive Sphygmomanometers Supplementary Requirements
- EN980-Symbols
- EN46001-Quality
- EN1441-Risk Analysis
- EN60601-1-2-EMC
- EN60601-1-Electrical Safety
- 93/42/EEC-MDD
- 89/336/EEC-EMC Directive
- 92/37/EEC-Product Safety
- 93/465/EEC-Conformity Assessment and CE Marking
- UL 2601-1-Safety US
- ISO 10993-1-Biological Evaluation
- ISO 9001:1994-Quality
- ISO 9001:2000-Quality
- ISO 13485:1996/1998-Medical Devices
- 21CFR Part801-Labeling
- 21CFR Part820-QSR
- FDA Blue Book Memorandum G95-1-Biocompatibility

The BPCard is a non-invasive Blood Pressure Monitor that measures blood pressure (systolic and diastolic) using the auscultatory method in both male and female, pediatric and adult subjects. The BPCard also measures heart rate. It is to be used by health care professionals in a hospital, clinic or home environment. It is contraindicated in patients who are not ambulatory, have heart failure, arrhythmia, or cardiac valve abnormality. It is not to be operated in an explosive atmosphere nor in proximity to any equipment that has the potential to generate a

sufficiently large electromagnetic field as to interfere in any manner with the operation of the BPCard.

The BPCard is a Prescription Device, *not* life supporting or live sustaining, *not* an implant, supplied *non*-sterile with a cuff, valve and microphone that requires a Personal Computer with the following requirements:

- Windows 2000 Operating System
- 32 MB RAM
- 1 GB Free Hard Disc Space
- 133 MHz Processor

E. Intended Use Statement

The BPCard can be used by health care professionals to measure blood pressure values (systolic and diastolic) and heart pulse rate in adults and children.

F. Components/ Part Numbers

- BPCard User's Manual – 6000-XXXX
- BPCard – PCMCIA Blood Pressure Monitor – 7000-XXXX
- Cuff, Valve, Bulb and Microphone – 5000-XXXX
- BPCard Software Version 1.0 – 9000-0088

G. Table of Comparisons

The following summary tables of comparisons compare the new device (BPCard) to the predicate device: Accutracker DX.

#	Area	New Device: BPCard™	Predicate Device: Accutracker DX	Same	Different
1	Non-Invasive Blood Pressure Monitor	NIBP	NIBP	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	Heart Rate	Heart Rate	Heart Rate	X	
5	Technique	Auscultatory	Auscultatory	X	
6	SP10 Conformance	Yes	Yes	X	
7	Accuracy	SP10 – Trained Observer	SP10 – Trained Observer	X	

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8	Power Source	Via Personal or Portable Computer (Battery)	Battery		X
9	Diastolic	5th Korotkoff Sound	5th Korotkoff Sound	X	
10	Weight	< 6 ounces	12.6 ounces		X
11	Size	53 x 140 x 26 W D H in mm	825 x 330 x 127 W D H in mm		X
12	Deflation	2-3 mm Hg/ second	2, 3, 4, 5 or 6 mm Hg/ Second		X
13	Operating Environment	10 to 40° C 15 - 95%	10 to 40° C < 95%	X	
14	Storage Environment	-20 to 50° C 15 – 95%	-20 - 50° C < 95%	X	
15	Certification	UL, CE	UL, CE	X	
16	Prink Reports	No	Yes		X
17	Safety Standards	Yes	Yes	X	
18	EMC	Yes	Yes	X	
19	Prescription Device	Yes	Yes	X	
20	Range Systolic	60-250 mm Hg	10-250 mm Hg		X
21	Diastolic Range	40-220 mm Hg	10-250 mm Hg		X
22	Bladder Deflation	Automatic	Automatic	X	
23	Programmable	No	Yes		X
24	Inflation Method	Bulb	Automatic		X
25	Part of System	No	Yes		X
26	Sampling	No	Yes		X
27	Cuff Sizes	Multiple	Multiple	X	
28	Clinical Reports	No	Yes		X
29	Print outs	No	Yes		X
30	Sampling Periods	No	Yes		X
31	510(k) Summary	Yes	No		X
32	Supplied Non-Sterile	Yes	Yes	X	

H. Discussion of Similarities and Differences

The BPCard and Accutracker DX have the following similarities:

- NIBP Monitor
- Patient Population
- Environment
- Heart Rate
- Technique
- SP10 Conformance

According to the FDA's NIBP Monitor Guidance "substantial equivalence can be demonstrated by showing either;

1. Sufficient comparison testing with a legally-marketed predicate device
2. Conformance to SP10 Standard
3. Conformance to any foreign or domestic standard which meets or exceeds the requirements of the SP10 Standard."

Furthermore, the FDA states, "It is strongly recommended that substantial equivalence be demonstrated by showing conformance to the SP10 Standard."

Thus, even though the BPCard is not identical to Accutracker DX, it *does* comply with the SP10 Standard and we at QRS believe it should be granted substantial equivalence by its conformance to SP10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

QRS Diagnostic, LLC.
c/o Ms. Mary Kay Jensen
14755 27th Ave. North
Plymouth, MN 55447

Re: K031964
Trade Name: BPCard™
Regulation Number: 21 CFR §870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 21, 2003
Received: June 25, 2003

Dear Ms. Jensen:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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

Enclosure

510(k) Number (if known): K031964

Device Name: BPCard

Indications For Use:

The BPCard is a non-invasive Blood Pressure Monitor that measures blood pressure (systolic and diastolic) using the auscultatory method in both male and female, pediatric and adult subjects. The BPCard also measures heart rate. It is to be used by health care professionals in a hospital, clinic or home environment. It is contraindicated in patients who are not ambulatory, have heart failure, arrhythmia, or cardiac valve abnormality. It is not to be operated in an explosive atmosphere nor in proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the BPCard.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031964

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)