K100155
P1/3

510(k) Summary of Safety & Effectiveness **Date: Jan 14, 2010**

1.) Submitter Name & Address:

Biomedical Systems, Inc
77 Progress Parkway
Maryland Heights, MO 63043

APR 20 2010

2.) Contact Person:

K. Michael Kroehnke
Phone: 314-576-6800
Fax: 877-581-7858

3) Device:

Trade Name: TruVue™ System

Classification Name: Arrhythmia Detector and Alarm

Product Code: DSI

Regulation No: 870.1025

Class: Class II, Special Controls

4) Substantial Equivalence:

The TruVue™ System is substantially equivalent to following previously cleared devices:

1) CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector, K081257
2) NUVANT, Mobile Cardiac Telemetry System, K091971
3) Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector, K090037

	TruVue™	**CG-6108 ACT-3L**	**PocketECG**	**NUVANT**	**SE Determination**
ECG Channels	2	2	1	1	SE, see note a
Ambulatory ECG performance standards	EC 38 compliant	EC 38 compliant	EC 38 compliant	EC 38 compliant	SE, see note b
ECG Acquisition / WAN communications	Body worn sensor, handheld WAN device	Body worn sensor, handheld WAN device	Body worn sensor, handheld WAN device	Body worn sensor, handheld WAN device	SE

Transmission Technology (PAN)	Bluetooth	Bluetooth	Bluetooth	Bluetooth	SE
Transmission Technology (WAN)	Cellular POTS Modem	Cellular POTS Modem	Cellular	Cellular	SE, see note c
User Event Trigger	Handheld user Interface	Handheld User Interface	Handheld User Interface	Patient Magnet	SE, see note d
Algorithm	Proprietary / Server side	Proprietary / Device side	Proprietary / Device side	Proprietary / Device side	SE, see note e

a) All predicates devices provide at least one channel of ECG, the minimum requirement cited in AAMI-EC38 for ambulatory arrhythmia monitoring.
b) All predicate devices meet the ECG performance requirements (or claim SE to a predicate device that meets the performance requirements) of AAMI EC-38 and are therefore SE.
c) All predicate devices use public communication networks for transmission of data to a monitoring center, whether cellular, POTS, or both and are therefore SE.
d) All predicate devices have a means for the patient to indicate a symptomatic event and are therefore SE.
e) All predicate devices contain an analysis algorithm with SE capabilities between the signal acquisition point and the reviewer of the data and are therefore SE.

5) Device Description

The TruVue™ system is a continuous ECG monitor and Arrhythmia detector. The system is comprised of a body worn sensor that collects, stores and transmits 2 channels of ECG, a handheld communications device that transmits the ECG to an attended monitoring center and analysis software that continuously analyzes the ECG signal for arrhythmia.

The sensor communicates with the handheld over a Bluetooth link, the handheld communicates with the data center over the cellular telephony network or a land line telephony network. Full disclosure ECG is available at the data center for use by the analysis algorithm or for review and further analysis by a monitoring technician or physician.

K100155
p 3/3

6) Indications for use

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Indications:

1. The TruVue System is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring
5. ECG data recorded by the device can be analyzed by other processing systems, such as the BMS Century Holter system to provide Holter style reports

Contraindications

The TruVue System is contraindicated for those patients requiring attended, In-hospital monitoring for life threatening arrhythmias.

Note

The TruVue system does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

7) Conclusions

The TruVue system has the same intended use, similar operating principles and similar technological characteristics as the predicate devices. As supported by the descriptive information and performance validation it is concluded that the TruVue system is as safe and effective as its predicates.

8) Referenced standards

FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

-IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety
-IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility
-AAMI EC 38-2007, Ambulatory Electrocardiographs
-ANSI/AAMI-EC 57:1998, Testing and Reporting - Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Biomedical Systems Corporation
c/o Mr. K. Michael Kroehnke
Director of Quality Management
77 Progress Parkway
St. Louis, MO 63043

APR 20 2010

Re: K100155
Trade/Device Name: TruVue™ Wireless Ambulatory ECG
Regulatory Number: 21 CFR 870.1025
Regulation Name: Detector and Alarm, Arrhythmia
Regulatory Class: II (two)
Product Code: 74 DSI
Dated: March 18, 2010
Received: March 19, 2010

Dear Mr. Kroehnke:

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 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); 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,

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

Enclosure

K100155

Indications for Use

510(k) Number (if known): K100155

Device Name: **TruVue™ Wireless Ambulatory ECG**

Indications For Use:

1. The TruVue™ System is intended for use by patients who experience transient events that may suggest cardiac arrhythmia
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems, such as the BMS Century Holter system to provide Holter style reports

Contraindications:
The TruVue™ System is contraindicated for those patients requiring attended, In-hospital monitoring for life threatening arrhythmias.

Note: The TruVue™ System does not provide interpretive statements. Interpretation and diagnosis is the responsibility of the physician.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100155