K101674 P1/2

Section 5 – Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

JUL 21 2010

Submission Date:	June 11th, 2010
510(k) Submitter/Holder:	Athena GTX 3620 SW 61st Street, Suite 395 Des Moines, Iowa 50321 Ph.: 515.288.3360 Fax.: 515.288.3394
Company Contact:	Sean Mahoney (Chief Technical Officer) Office Phone Number: 515.288.3360 Email: smahoney@athenagtx.com
Trade Name:	WVSM Wireless Vital Signs Monitor
Common Name:	Cardiac Monitor
Classification Name:	Cardiac Monitor (Including cardiotachometer and rate alarm) (Refer to 21 CFR 870.2300) NIBP Measurement System (Refer to 21 CFR 870.1130 Oximeter (Refer to 21 CFR 870.2700) Radiofrequency Physiological Signal Transmitter and Receiver (Refer to 21 CFR 870.2910)
Classification Regulation:	Class II
Basis for Submission:	New device design
Legally Marketed (Predicate) Devices:	Welch Ally Propaq LT Vital Signs Monitor, (K033378) Nonin Medical, Inc. Model # 7500 Digital Pulse Oximeter (K071285) HomMed Genesis Patient Monitor System (K040799) Welch Allyn Acuity Central Monitoring Station (K052160, K022453)
Device Description:	The Athena GTX (WVSM) Wireless Vital Signs Monitor is a small, lightweight, rugged, and highly portable patient monitor designed to measure SpO_2, NIBP and ECG. Vital signs are displayed directly on the device, and may be transmitted via WiFi 802.11b/g radio frequency

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	communication to a Personal Computer (PC) or Personal Digital Assistant (PDA).
Predicate Device Overview:	The WVSM is designed for the same application and intended use as the combination of listed predicate devices. The WVSM is capable of the same ECG, heart rate, systolic and diastolic blood pressure, functional oxygen saturation, and pulse rate measurements as have been provided by the combination of predicate devices referenced above.
Intended Use:	The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2. It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer. The monitor is intended to be used by trained healthcare providers.
Summary of Testing:	Testing On the WVSM 5.0 has been completed to verify compliance with recognized national and international standards for safety and performance for medical devices, and particular requirements applicable to this device
Conclusion:	Based on the results for all safety and compliance testing performed, it is the opinion of Athena GTX the WVSM Wireless Vital Signs Monitor is safe and effective, and is substantially equivalent to the above listed predicate devices.

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

Mr. Sean Mahoney
Chief Technical Officer
Athena GTX
3620 SW 61st Street, Suite 395
Des Moines, Iowa 50321

JUL 21 2010

Re: K101674
Device Name: Athena GTX Wireless Vital Signs Monitor (WVSM)
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (Without Arrhythmia Detection or Alarms)
Regulatory Class: Class II (Two)
Product Codes: MWI, DQA, DXN, DRG
Dated: June 14, 2010
Received: June 15, 2010

Dear Mr. Mahoney:

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.

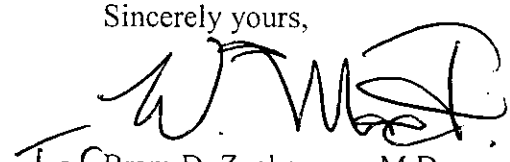
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

Section 4 - Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K101674

Device Name: Wireless Vital Signs Monitor

Indications for Use:

The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2. It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer. The monitor is intended to be used by trained healthcare providers.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

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