K101983
p1/2

Critical Patient Care, Inc.

SEP 21 2010

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: _____

1. Applicant Information:

Date Prepared:	December 15, 2009
Name:	Critical Patient Care, Inc.
Address:	4005 Blackhawk Street Edinburg, TX 78539
	Phone: 1 888-874-7608
Contact Person:	Marie Cosgrove
Phone Number:	210-810-9062
Fax Number:	877 321 5676
	mariecosgrove@criticalcareassessment.com

2. Device system Information:

Classification:	JOM/ClassII/870.2780
Trade Name:	'Critical Care Assessment'
Common Name:	Plethysmograph, photoelectric, pneumatic or hydraulic
Regulation Number:	21 CFR 870.2780

3. Substantial Equivalence:

ANSHA -QHRV1	K083735
Reason for submission:	Re-labeling device under new trade name.
Performance:	The functions are substantially equivalent to the predicate.

4. Intended Use:

'Critical Care Assessment' is intended for noninvasive measurements of pulse waveforms by photoelectric plethysmography and heart rate electrocardiograph. The system is intended for use of patients in medical clinics, healthcare practices and in out-patient department of hospitals.

5. **Description of the Device**

Critical Care Assessment device is a microprocessor based, monitor biomedical acquisition system – it identifies, classifies, and collects ECG and Plethysmograph signals from the human body. The analog signals are converted to digital data and transferred to the personal computer via isolated USB connection. This isolation separates the human body from the main power system to ensure maximum patient safety. The patient data collected from the unit is used to perform Heart Rate Variability Analysis and obtain several detailed assessment of the Autonomic Function (Autonomic Nervous System Balance), Blood flow, Stress, Fitness and the overall health risk analysis.

6. **Comparison to Predicate Device:**

All materials used have gone through the same identical performance testing as the legally marketed predicate device 'ANSHA-QHRV1' marketed under 510k K083735. Both devices are identical in all areas of design, materials used, software, function and application to the predicate device and have undergone through the same performance testing. The only difference is the labeling of the device.

7. **Comparison Summary of Non-Clinical Data Submitted:**

Critical Care Assessment has met the requirements for QRS Detection and Heart Rate Variability & Algorithm Verification (ANSI-AAMI EC57-98). Met the General Requirements for Safety and Collateral Standard Safety Requirements for Medical Electrical Systems (IEC 60601-1 (1998) with Am. 1 (1991), Am. 2 (1995). Also, complies with Electromagnetic Compatibility Test (UL 60601-1 (2003). This performance testing is identical to the predicate device.

8. **Argument for Substantial Equivalence to Predicate Devices**

The intended use and the technological characteristics of Critical Care Assessment™ are the same as the predicate device and therefore we believe it is Substantially Equivalent to it.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Critical Patient Care, Inc.
c/o Ms. Paula Wilkerson
Sr. Reviewer, Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

SEP 21 2010

Re: K101983
Trade/Device Name: Critical Care Assessment
Regulatory Number: 21 CFR 870.2780
Regulation Name: Plethysmograph, Photoelectric, Pneumatic or Hydraulic
Regulatory Class: II (two)
Product Code: JOM
Dated: September 3, 2010
Received: September 7, 2010

Dear Ms. Wilkerson:

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,

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

Enclosure

K101983

Critical Patient Care, Inc.

SEP 21 2010

Indications for Use

510K Number (if known) K101983

Device system Name: 'Critical Care Assessment'

Indications for Use: 'Critical Care Assessment' is intended for noninvasive measurements of pulse waveforms by photoelectric plethysmography and heart rate electrocardiograph. The system is intended for use of patients in medical clinics, healthcare practices and in out-patient department of hospitals.

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)

Description of the Device Donna R. Vickery

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101983