K110192

FEB 8 2011

5 510(k) Summary (As required by 21 CFR 807.92)

Date Prepared: November 2, 2010

Submitter's Information:

Submitter's Name/ Address	BC Group International, Inc 3081 Elm Point Industrial Drive St. Charles, MO 63301
Owner/Operator	BC Group International, Inc 3081 Elm Point Industrial Drive St. Charles, MO 63301 USA
Manufacturing Sites	BC Group International, Inc 3081 Elm Point Industrial Drive St. Charles, MO 63301 USA FDA Establishment Registration Number: Pending

Submission Contact Information:

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Proposed Device

Device Proprietary Name:	DA-2006P
Classification Name	Defibrillator Tester
Class	Class II/21CFR 870.5325
Product Code	DRL

Predicate Devices

- Metron QA-40/45M Defibrillator Tester (K963190)

Section 514 Compliance

Not applicable. Special Controls have not been established as of this date.

Indications for Use

The DA-2006/DA-2006P are used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through the measurement of energy output. The DA-2006 tests defibrillators while the DA-2006P additionally tests transcutaneous pacemakers.

Description of Device

The BC Group International DA-2006 Defibrillator Tester is a precision instrument for testing defibrillators, and for ensuring that defibrillators comply with specified requirements.

The DA-2006 is a microprocessor-based instrument that is used in the testing of defibrillators. It measures the energy output and provides information about the pulse. It is used on manual, semi-automatic and automatic defibrillators with monophasic or biphasic outputs.

The DA-2006P model additionally provides a Transcutaneous Pacemaker analysis function. It measures and displays pacer pulse information as well as performing Refractory Period, Sensitivity and Immunity testing.

All models have a built in 50 ohm human body simulation load as well as 12 lead ECG with arrhythmias and performance waveforms. Additionally, they have a centronics printer port, a serial port, oscilloscope output, high level ECG output, as well as provision for a battery eliminator.

The DA-2006P makes viewing and selecting the desired waveforms and test data quick and intuitive, with all operational information being available on the 240 by 64 pixel graphic display, allowing for easy maneuvering through parameters and scrolling through available options.

NOTE: The instrument is intended for use by trained service technicians.

Comparison to Predicate Device

The DA-2006P Defibrillator Tester uses the same exact approach and DUT evaluation procedures as the predicate device.

Summary of Technical Characteristics

The DA-2006P Defibrillator Tester shares the same technological characteristics; design, materials, and composition as the predicate device.

Summary of Non-Clinical Testing/Statement of Equivalence

The DA-2006P Defibrillator Tester was tested to meet international standards for electromagnetic compatibility and electrical safety. Verification and Validation tests were performed to ensure that all of the product specifications were met.

The testing performed indicates that the DA-2006P is as safe and as effective as the predicate device. Table 2 below shows the extent of the testing that was performed.

Table 2: Device Test Summary

Test	Description	Result
EN61326	Electrical equpment for measurement, control, and laboratory use - EMC Requirements	Pass
EN61000-3-2	Electromagnetic Compatibility (EMC) Part 3-2 Limits - Limits for Harmonic Current Emmistions	Pass
EN61000-3-3	Electromagnetic Compatibility (EMC) – Part 3: Limits – Section 3: Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems	Pass
IEC61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General Requirements	Pass

Test	Description	Result
Debugger Validation	Evaluate device operation under conditions not available under normal use	Pass
Device Validation	Validate device function of each hardware and software specification	Pass
Device Verification	Ensure device function during assembly.	Pass

Conclusion

In conclusion, the results from the nonclinical testing demonstrate that the DA-2006P Defibrillator Tester is as safe, as effective, and performs as well as the predicate device.

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

FEB 8 2011

Intertek Testing Services NA, Inc.
C/O Paula Wilkerson
Sr. Staff Engineer
2307 E Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K110192
Trade/Device Name: Defibrillator Analyzer- DA-2006 and Transcutaneous Pacemaker Tester DA-2006P
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL
Dated: January 20, 2011
Received: January 24, 2011

Dear Ms. Paula 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. 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.

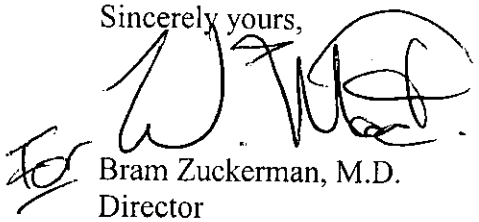
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Statement of Indications for Use

510(k) Number (if known): Unknown

Name of Devices: DA-2006 and DA-2006P Defibrillator Tester

Indications for Use:

The DA-2006/DA-2006P are used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through the measurement of energy output. The DA-2006 tests defibrillators while the DA-2006P additionally tests transcutaneous pacemakers.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110192