



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 21, 2015

BC Group International, Inc.
% Mel Roche
President
3081 Elm Point Industrial Drive
Saint Charles, Missouri 63301

Re: K153210

Trade/Device Name: Defibrillator Analyzer Variable Load, Model DA-2006-VL
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL
Dated: July 17, 2015
Received: November 5, 2015

Dear Mel Roche:

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

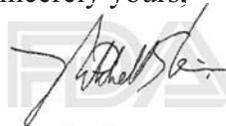
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 Industry and Consumer Education 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

Indications for Use

510(k) Number (if known)

K153210

Device Name

DA-2006-VL Defibrillator Analyzer Variable Load

Indications for Use (Describe)

The DA-2006-VL is used to determine that defibrillators are performing within their performance specifications by providing multiple loads of 25, 50, 75, 100, 125, 150, 175 and 200 Ohms. The DA-2006-VL is used in conjunction with the DA-2006/DA-2006P.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5 The CDRH Premarket Review Submission Cover Sheet for the DA-2006-VL Variable Load is contained in this section 510(k) Summary (As required by 21 CFR 807.92)

Date Prepared: February 1, 2015

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: 2939012

Submission Contact Information:

Primary Contact	Name	Mel Roche
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Proposed Device

Device Proprietary Name:	DA-2006-VL Defibrillator Analyzer Variable Load
Classification Name	Defibrillator Tester Variable Load
Class	Class II/21CFR 870.5325
Product Code	DRL

Predicate Devices

Fluke Impulse 7010 Defibrillator Selectable Loads (K083347)

Section 514 Compliance

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

Indications for Use

The DA-2006-VL is used to determine that defibrillators are performing within their performance specifications by providing multiple loads of 25, 50, 75, 100, 125, 150, 175 and 200 Ohms. The DA-2006-VL is used in conjunction with the DA-2006/DA-2006P.

Description of Device

The BC Group International DA-2006-VL Variable Load is a precision instrument for testing defibrillators, and for ensuring that defibrillators comply with international standards IEC 60601-2-4 and AAMI DF80.

The DA-2006-VL is a non-powered, selectable resistive load bank. Through various series and parallel resistor combinations, the DA-2006-VL allows a user to select 25, 50, 75, 100, 125, 150, 175, and 200 Ohm loads.

The DA-2006-VL is used in conjunction with the DA-2006/DA-2006P Defibrillator Analyzer.

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

Comparison to Predicate Device

The DA-2006-VL Variable Load uses the same exact approach and DUT evaluation procedures as the predicate device.

Summary of Technical Characteristics

The DA-2006-VL Variable Load shares the same technical characteristics; design, materials, and composition as the predicate device.

Summary of Technological Characteristics in Comparison with the Predicate Device

Table 2: Predicate Feature Comparison			
	Device Feature or Characteristic	Fluke Impulse 7010	BC Biomedical DA-2006-VL Specifications
General Specifications	Maximum voltage	5000 V	5000 V
	Maximum Continuous Power	12 W, 10 defib pulses of 360 J every 5 minutes	12 W, 10 defib pulses of 360 J every 5 minutes
	Inductance	< 2 μ H, @25 Ω < 3 μ H, @50 Ω < 4 μ H, @75 Ω and 100 Ω < 5 μ H, @125 Ω < 6 μ H, @150 Ω < 7 μ H, @175 Ω < 8 μ H, @200 Ω	< 10 μ H
Electrical Specifications	Load Settings	25, 50, 75, 100, 125, 150, 175, 200 Ohms, \pm 1%	25, 50, 75, 100, 125, 150, 175, 200 Ohms, \pm 1%
	Accuracy (50 Ω)	\pm 1% of reading + 0.1 J	<u>High Range</u> \pm 2 % of reading for >100 Joules \pm 2 Joules for \leq 100 Joules <u>Low Range</u> \pm 2 % of reading for >20 Joules \pm 0.4 Joules for \leq 20 Joules

Table 2: Predicate Feature Comparison			
	Device Feature or Characteristic	Fluke Impulse 7010	BC Biomedical DA-2006-VL Specifications
	Accuracy (25 Ω, 75-200 Ω)	± 2% of reading + 0.1 J	<u>High Range</u> ± 3 % of reading for >100 Joules ± 3 Joules for ≤100 Joules <u>Low Range</u> ± 3 % of reading for >20 Joules ± 0.6Joules for ≤20 Joules
Physical	Dimensions	138.7 mm x 154 mm x 272 mm	248.9 mm x 205.7 mm x 120.7 mm
	Weight	1.54 kg	2.27 kg
	Operating Temperature	10 to 40 C	15 to 40 C
	Storage Temperature	-20 to +60 C	-20 to +65 C

- there are 7 differences,
- there are 0 features where a comparison cannot be made due to lack of predicate specifications,
- there are 3 features where the DA-2006-VL is identical to the predicate.

Overall, the devices are very similar, with the 6 differences not having any effect on the indications for use or the device's safety. There are a few minor effects on the performance characteristics of the device; some of these are discrepancies in size, weight, and accuracy. The DA-2006-VL is heavier than the predicate device and is slightly less accurate.

None of the differences raise new questions of safety or effectiveness.

Summary of Non-Clinical Testing/Statement of Equivalence

The DA-2006-VL Defibrillator Tester was tested to meet international standards for electrical safety. Since the DA-2006-VL is a non-powered, manually selectable resistive load, it is exempt from electromagnetic compatibility testing. Verification and Validation tests were performed to ensure that all of the product specifications were met.

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

Table 3: Device Test Summary

Test	Description	Result
IEC61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General Requirements	Pass
Device Validation	Validate device function of each hardware specification	Pass
Device Verification	Ensure device function during assembly.	Pass

Conclusion

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