K082861

BraunSolutions®

K_____

510(k) Summary
(Per 21 CFR 807.92)

NOV 25 2008

Submitter/Owner:

Amco International Manufacturing & Design, Inc.
Attn: Mr. Adam Milewski
Medical Battery Division
10 Conselyea Street,
Brooklyn, NY 11211 USA

Official Correspondent:

Alexander B. Henderson
BraunSolutions
377 Zane Court,
Elizabeth, CO 80107 USA
Tel: 303-646-3715
Email: alex_henderson@msn.com

Date Prepared: September 22, 2008

Device Name:

Trade/Proprietary Name: AMCO™ Battery Pack
Common/Generic Name: Box, Battery
Classification Name: Box, Battery, Non-Rechargeable
Regulatory Class III, Product Code MKJ

Predicate Devices:

Cardiac Science Replacement Battery 9141-001
- Approved under K031987 and K040438
Cardiac Science Replacement Battery 9146-001
- Approved under K031987 and K040438

Classification:	**Cardiovascular Panel**	**Class**
21 CFR 870.5300	DC-Defibrillator	III
21 CFR 870.5310	Automated External Defibrillator	III

377 Zane Court • Elizabeth, Colorado USA 80107
Telephone / Fax: 303-646-3715 • Email: alex_henderson@msn.com

K082861

510(k) Summary

AMCO Replacement Battery Packs
2L561 and 7L877

Legally Marketed Predicate Devices:

The Amco 2L561 is the same as the Cardiac Science replacement battery Model and / or Part Number 9141-001 used in the Cardiac Science PowerHeart® AED cleared under 510(k) notification K031987 and K040438.

The Amco 7L877 is the same as the Cardiac Science replacement battery Model and / or Part Number 9146-001 used in the Cardiac Science PowerHeart® AED G3 cleared under 510(k) notification K031987 and K040438.

The Cardiac Science battery packs were most likely bundled in the original submission(s) as accessories.

Device Description:

Non-rechargeable battery packs are utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment. These devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current used by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and the discharge method. These parameters are taken into account in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible under a specified range of environmental conditions.

Statement of Intended Use:

To power the specific Cardiac Science AED's for which these battery packs are intended. Only qualified personnel, such as Biomedical Engineers, Medical Clinics, EMT's, etc., should evaluate, test, or install these battery packs.

Substantial Equivalence:

The design components and functionality of the AMCO™ 2L561 and 7L877 Battery Packs are identical to those of their predicate devices. Cell chemistry and type are identical, Sealed (Vented) Lithium Sulfur Dioxide (LiSO2). The only difference between the devices is that the 7L877 (9146-001) is designed specifically for the PowerHeart® G3 AED. Therefore, the molded plastic case has a stub (key) in order that it cannot be installed in the PowerHeart® AED requiring the 2L561 (9141-001). Both Amco Battery Pack models can be used in the Cardiac Science PowerHeart® G3 AED.

Reference: Substantial Equivalence Comparison Charts – Section B, Page 1.

377 Zane Court • Elizabeth, Colorado USA 80107
Telephone / Fax: 303-646-3715 • Email: alex_henderson@msn.com

K082861

510(k) Summary

AMCO Replacement Battery Packs
2L561 and 7L877

Conclusions:

Amco International Manufacturing and Design, Inc. has demonstrated through its continued evaluation and testing of the AMCO™ 2L561 and 7L877 Replacement Battery Packs, that these devices are equivalent to the current PowerHeart® Series AED Replacement Battery Packs, as outlined in this submission. The proposed AMCO™ 2L561 and 7L877 Battery Packs are identical with respect to indications for use, technological characteristics, materials, form. fit, and function to those currently distributed commercially. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission

377 Zane Court • Elizabeth, Colorado USA 80107
Telephone / Fax: 303-646-3715 • Email: alex_henderson@msn.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Amco International Manufacturing & Design, Inc.
c/o Mr. Alexander B. Henderson
Braun Solutions
377 Zane Court
Elizabeth, Colorado 80107

NOV 25 2008

Re: K082861
Trade/Device Name: AMCO Replacement Battery Packs 2L561 and 7L877
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: September 22, 2008
Received: September 29, 2008

Dear Mr. Henderson:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K082861

Device Name: AMCO Replacement Battery Packs 2L561 and 7L877

Indications for Use:

The 2L561 Lithium Sulfur Dioxide (LiSO2) AMCO battery is a disposable replacement battery pack for use in the Cardiac Science PowerHeart® AED; specifically Cardiac Science Model / Part Number 9141-001. This battery has a shelf life of 4 years from the date of manufacture.

The 7L877 Lithium Sulfur Dioxide (LiSO2) AMCO battery is a disposable replacement battery pack for use in the Cardiac Science PowerHeart® AED G3; specifically Cardiac Science Model / Part Number 9146-001. This battery has a shelf life of 4 years from the date of manufacture.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 807 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 K082861