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

July 14, 2017

Anybattery, Inc.
% Claude Berthoin
President
Denterprise International, Inc./510k FDA Consulting
100 East Granade Blvd., Suite 219
Ormond Beach, Florida 32176

Re: K160667
Trade/Device Name: Anybattery C2 Rechargeable Battery, with list of 28 models attached
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, LOS, LDD, DRT, MHX, DSI, MLD, MSX, MWI, DQK, DXH, FLL, DQA, DSJ, DSK, DSF, BZQ, and DXN
Dated: April 5, 2016
Received: April 11, 2017

Dear Claude Berthoin:

This letter corrects our substantially equivalent letter of May 11, 2017.

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" (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 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,

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

Enclosure

Anybattery, Inc.
List of all batteries cleared in K160667

(Total of 28 battery models, due to some batteries being grouped together under one predicate)

Anybattery C2 Rechargeable Batteries in the VRLA Product Family.

1. Anybattery 3394 is substantial equivalent to that manufactured by:
   - Zoll D-900 defibrillator cleared K913484.

2. Anybattery 4028 is substantial equivalent to that manufactured by:
   - Hewlett-Packard Pagewriter XLI M1700A & Pagewriter XL M1701A cleared K895520.

3. Anybattery 4040 is substantial equivalent to that manufactured by:
   - HP 43100 series defibrillator monitors cleared K910754.

4. Anybattery 4043 is substantial equivalent to that manufactured by:
   - Hewlett-Packard Monitor, Patient Model 78333A cleared K760160.

5. Anybattery 4494 is substantial equivalent to that manufactured by:
   - Physio-Control LifePak 9 Defibrillator & Cardiac Monitor cleared K881153.

6. Anybattery 4494-2 is substantial equivalent to that manufactured by:
   - Physio-Control LifePak 9 series defibrillator monitors cleared K902288.

7. Anybattery 4510 is substantial substantially equivalent to that manufactured by:
   - Welch Allyn Protocol Propaq cleared K012451.

8. Anybattery 4713-2 is substantial equivalent to that manufactured by:
   - Physio-Control Lifepak 10 defibrillator cleared K931053.

9. Anybattery 5349-4 is substantial equivalent to that manufactured by:
   - Nihon-Kohden TEC-7511A/TEC-7521A CardioLife Portable Defibrillator & Accessories cleared K971436.

10. Anybattery 6558 is e substantial equivalent to that manufactured by:
    - Spacelabs Healthcare Telemetry Receiver cleared K141156 & K925510.

11. Anybattery 7714-1 and 7714-2 are substantial equivalent to that manufactured by:
    - Colin Pressmate PM2100 VSM cleared K022537.

12. Anybattery 8601 is substantial equivalent to that manufactured by:
    - Welch Allyn Atlus Monitor cleared K984033.

Anybattery C2 Rechargeable Batteries in the Nickel-Based Rechargeable Battery Product Family

1. Anybattery 3777 is substantial equivalent to that manufactured by:
   - Burdick EK10 Series ECG cleared K870880.

2. Anybattery 4218 is substantial equivalent to that manufactured by
   - General Electric MAC Series Electrocardiographs cleared K991735.

3. Anybattery 4227 is substantial equivalent to that manufactured by:
   - Marquette Eagle 4000 Patient Monitor cleared K964750.

4. Anybattery 5960 is substantial equivalent to that manufactured by:
   - Schiller AT-5 cleared K941462.

5. Anybattery 6459, 7062-1 and 7062-2 are substantial equivalent to that manufactured by:
   - Burdick Eclipse Series ECG cleared K943959 & K946281.

6. Anybattery 7023 is substantial equivalent to that manufactured by:
   - General Electric MAC Series Electrocardiographs cleared K991735.

7. Anybattery 7038 is substantial equivalent to that manufactured by:
   - Spacelabs Medical Patient Monitors cleared K102422.

8. Anybattery 7050 is substantial equivalent to that manufactured by:
   - Critikon Dinamap Pro 1000 Monitor cleared K002248.

9. Anybattery 7059 is substantial equivalent to that manufactured by:
   - BCI Intl., Inc. 6004 NIBP Monitor cleared K983796 & K984618.

10. Anybattery 7171 is substantial equivalent to that manufactured by:
    - Nihon Kohden ECG-1250A Series and ECG-1350A Series ECGs cleared K072217.

11. Anybattery 7711 is substantial equivalent to that manufactured by:
    - Nihon Kohden BSM-2300A Series Bedside Monitor cleared K011918.

12. Anybattery 7726 is substantial equivalent to that manufactured by
    - CAS Medical 740 Series Monitor cleared K033048.

13. Anybattery 7732 is substantial equivalent to that manufactured by:
    - Cardiac Science Atria 3100, 6100 cleared K060167.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160667

Device Name

Anybattery Battery Pack

Indications for Use *(Describe)*

To power the functions of various devices for which batteries or battery packs are configured.

Since rechargeable batteries and battery packs are "device specific" and are designed to operate and fit into the equipment for which they were manufactured only qualified personnel should evaluate, test, charge, or install these devices.

Battery Packs are is shipped only to customers who request a replacement battery for a particular device or to replace a competitor's battery. The biomedical equipment technician therefore knows the intended use is as a replacement battery.

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.

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510k FDA Consulting
Medical Device Clearance

100 East Granada Blvd., Suite 219 Ormond Beach, FL 32176 386-506-8711

510 (k) Summary

I. Submitter/Applicant

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Point of Contact: Edward J. Speegle, (ed@anybattery.net)

Preparer/Consultant

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Fax: 386-672-4402
Primary Contact: Joyce St. Germain, Regulatory Assistant (joyce@510kfda.com)
Secondary Contact: Claude Berthoin, President (joyce@510kfda.com)
Preparation Date: March 3, 2016

II. Device Classification

Trade Name: Anybattery C2 Rechargeable Battery
Common Name: Box Battery or Pack Battery
Submission Type: 510(k)
Regulatory Class: II
Classification Name: Box Battery, Rechargeable
Panel: Cardiovascular

Product Code	Regulation	Device
DPS	21CFR870.2340	Electrocardiograph
LDD	21CFR870.5300	Dc-Defibrillator, Low-Energy, (Including Paddles)
DRT	21CFR870.2300	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)
MHX	21CFR870.1025	Arrhythmia Detector and Alarms
DXN	21CFR870.113	System, Measurement, Blood-Pressure, Non-Invasive
MWI	21CFR870.2300	Monitor, Physiological, Patient (without Arrhythmia Detection or Alarms)
LOS		Unclassified, pre-amendment device
DSI	21CFR870.1025	Arrhythmia Detector and Alarm
MLD	21CFR870.1025	Arrhythmia Detector and Alarm
MSX	21CFR870.2300	Cardiac Monitor
DQK	21CFR870.1425	Programmable Diagnostic Computer
DXH	21CFR870.2920	Telephone Electrocardiograph Transmitter and Receiver
FLL	21CFR880.2910	Clinical Electronic Thermometer
DQA	21CFR870.2700	Oximeter
DSJ	21CFR870.1100	Blood Pressure Alarm
DSK	21CFR870.1110	Blood Pressure Computer
DSF	21CFR870.2810	Paper Chart Recorder
BZQ	21CFR868.2375	Breathing Frequency Monitor

III. Predicate Device

This submission compares the specifications and functionally of various rechargeable battery packs with those of similar devices that were included as part of the following original predicate devices and submissions.

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13. Anybattery 7732 is substantial equivalent to that manufactured by:

- Cardiac Science Atria 3100, 6100 cleared K060167.

IV. Device Description

Batteries have become a critical component in many medical devices. As more devices are computerized and more have become mobile, batteries play an important part in system performance and reliability. Medical batteries are treated as a piece of medical equipment, they are entered as an asset into the facilities equipment database and our included in the preventative maintenance schedule. The end use of the equipment is used to establish the frequency for preventative maintenance. Both the recommendation of the manufacturer of the medical device and the battery spec sheet from the battery manufacturer help establish the maintenance protocol.

Anybattery C2 Rechargeable batteries and 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.

Anybattery C2 Rechargeable batteries and battery packs either the primary or secondary source of power and they retain critical parameters and data in the event of power

disruption. These batteries range in size, while they are mostly 12-volt, they range in capacity from two-amp hour right up to 36-amp hour batteries.

The performance and life span of a rechargeable battery depends on several factors. Battery operating conditions of temperature, current drain, and charge/discharge method, are taken into account in the design of such batteries. Anybattery's goal is to develop a battery that maintains its battery capacity as high as possible and as long as possible.

There are several types of rechargeable batteries introduced and marketed for medical uses. In this submission are batteries in the Nickel-Based Rechargeable Battery Product Family and the Valve-Regulated Lead-Acid (VRLA) Rechargeable Battery Product Family.

Nickel-Based Rechargeable Battery Product Family

- The Nickel-Cadmium battery (NDC) is the most widely used rechargeable battery. Its efficient charge and discharge characteristics, reliability and economic nature have made it very popular and widely utilized in the medical industry. Manufacturers have developed nickel-cadmium batteries that can be charged up completely in one hour**.**
- The Nickel Metal Hydride (NMH) battery is a new technology being-worked on that can provide a 50% increase in energy density compared to Nickel Cadmium batteries. The Lithium battery recently introduced with energy densities of greater than twice that of NiCad batteries.

VRLA Rechargeable Battery Product Family

The Valve-Regulated Lead-Acid (VRLA) battery more commonly known as a sealed battery (SLA) is a type of lead-acid rechargeable battery. Due to their construction, the Gel and AGM types of VRLA can be mounted in any orientation, and do not require constant maintenance. There are three primary types of VRLA batteries, Sealed VR wet cell, AGM and Gel. Gel cells add silica dust to the electrolyte, forming a thick putty-like gel. These are sometimes referred to as "silicone batteries". AGM (absorbed glass mat) batteries feature fiberglass between the battery plates, which serves to contain the electrolyte. Both designs offer advantages and disadvantages compared to conventional batteries and sealed VR wet cells, as well as each other.

V. Indications for Use [Same as Intended Use]

To power the functions of various devices for which batteries or battery packs are configured.

Since rechargeable batteries and battery packs are "device specific" and are designed to operate and fit into the equipment for which they were manufactured only qualified personnel should evaluate, test, charge, or install these devices.

Battery Packs are shipped only to customers who request a replacement battery for a particular device or to replace a competitor's battery. The biomedical equipment technician therefore knows the intended use is as a replacement battery.

VI. Comparison of Technological Characteristics

The design components and functionality of the various batteries and battery packs included in this submission are similar to those of their predicate devices. Typical cell chemistries are Sealed -Lead Acid (SLA), Nickel-Cadmium (NiCad), and Nickel-Metal Hydride (NiMH). Both the new devices and the predicate 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 which they are installed. The performance and life span of the new devices and the predicate devices depends on operating conditions of temperature, current drain, and the charge/discharge method (if applicable). These parameters are taken into account in designing such batteries. The goal of all battery manufacturers is to develop batteries and battery packs that maintain capacity for as high and as long as possible. In comparison analysis, OEM Battery Packs (Predicate devices) set the benchmark and the Anybattery batteries replacement devices met and/or exceed the benchmark.

VII. Performance Data

Battery Pack Testing

General Protocol. The same battery testing protocol is used by the manufacturers of the predicate devices and the new devices.

Incoming Inspection

All cells are inspected for correct specification, visible damage, and randomly voltage tested prior to acceptance. The lot numbers are recorded for tracking purposes should any fail during final assembly and inspection activities. Cases are also inspected for form, fit, function, and cosmetics.

Vencon Testing

Voltage and capacity of battery cells and packs are tested using Vencon UBA Battery Analyzers in the "Test Mode" upon full completion of battery assembly design. This exercises the batteries in order to identify performance characteristics by running them through three (3) full charge/discharge cycles in the NKL based family and two (2) full cycles in the VRLA family. Tests typically take 12~48 hours for each battery pack.

All battery chemistries can be tested using custom test parameters, depending on Quality Control and customer requirements. This allows for various C -Rates, delta V (l:N), and volts-per-cell to be entered into the test protocol through the Vencon UBA Software (Reference UBA Test Report Examples - Figures 1 and 2)

Target capacity is the percentage of the battery capacity compared to nominal capacity and serves as a threshold. This threshold, or target capacity, can be set to any desired range (90 - 95% is typical).

Target capacity is a pass/fail mark for design acceptance. Our batteries must meet or exceed a required threshold of 90%, or higher, prior to final design control acceptance. Any samples that do not meet the criteria are rejected. Batch build sheets require 100% >then cutoff voltage, and polarity testing. Subsequently, the entire lot is tested and documented in this manner.

Battery packs are shipped in various states of dis-charge. There are specific DOT, FAA, and EPA regulations and guidelines that address these concerns.

Voltage Testing - Completed Packs

All Battery Packs are tested 100% for correct voltage and polarity prior to shipment. Those devices that fail are rejected and quarantined.

Safety and Performance

Safety and performance testing of battery packs are performed to ensure that these devices meet all functional requirements and performance specifications. In comparison analysis, OEM Battery Packs set the benchmark. Replacement devices must meet or exceed these benchmark results consistently.

Concerns that are addressed during bench test comparison analysis are:

- Life cycle

The replacement battery must provide as many or more charge and discharge cycles as the original. This is an ongoing process and is not part of the standard QC final inspection protocol. The cycle life is based on cycles under criteria set forth in IEC61951-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Portable sealed rechargeable single cells. Part 2: Nickel-Metal hydride and IEC 61056-1 General purpose lead-acid batteries (valve-regulated types) Part 1: General requirements, functional characteristics – Methods of test. As there is no internationally recognized shelf life determination, it is determined the device life shall be 12 months from point of sale.

- Temperature

The replacement battery must function correctly over the same temperature range as compared to the original. Testing is done at 0, 25, and 40°C (32, 77, and 104°F respectively).

- Mechanical & Electrical Component Integrity

Normal testing would involve drop tests from a predetermined height, usually 2-3 feet, onto a hard, uniform surface. Battery packs are inspected for case cracks, cell separation, and electrical/electronic component damage. Root cause analysis is performed should any damage occur.

VIII. Conclusion

In conclusion, Anybattery C2 Rechargeable batteries and battery packs are the substantial equivalent to the predicate devices. Anybattery C2 Rechargeable batteries and battery packs are the substantial equivalent in design, function and intended use to their predicate devices. In comparison analysis, the predicate batteries and battery packs set the benchmark and Anybattery C2 Rechargeable batteries and battery packs met or exceed the predicate devices in design and functionality, material, safety and performance, packing protocol, principal of operation, mechanical capacity, and physical properties, i.e., dimension, weight, voltage, discharge capacity, impedence and storage and device life. It is deemed after a comprehensive comparison analysis that Anybattery C2 Rechargeable batteries and battery packs are the substantial equivalent to the predication devices.