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

September 27, 2017

Peerbridge Health Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K171936
Trade/Device Name: Peerbridge Cor™ System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: September 19, 2017
Received: September 20, 2017

Dear Mark Job:

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 (DICE) 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 (DICE) 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

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)*
K171936

Device Name
Peerbridge Cor™ System

Indications for Use *(Describe)*
The Peerbridge Cor™ System family of products is intended to capture and transmit symptomatic events and continuous external electrocardiogram (ECG) information for 24 hours and up to 7 days (long term monitoring). The Peerbridge Cor™ System contains a continuous external electrocardiogram (ECG) recorder with a patient-activated events button. It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, fatigue, or anxiety. The reported ECG metrics supports 2-channel ECG analysis on a beat-by-beat basis, heart rate measurement and rhythm analysis by FDA cleared algorithms. The report generated does not contain diagnostic interpretation; the report is provided for review by intended users to render a diagnosis based on their clinical judgment and experience.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Notification K 171936

### GENERAL INFORMATION [807.92(a)(1)]

**Applicant:**

Peerbridge Health Inc.
1440 Broadway, 23rd Floor
New York, NY 10018
USA
Phone: 925-260-2096

**Contact Person:**

Anna Libman
Regulatory Consultant to Peerbridge Health, Inc.
Director, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA

**Date Prepared: May 15, 2017**

### DEVICE INFORMATION [807.92(a)(2)]

**Trade Name:**

Peerbridge Cor™ System

**Generic/Common Name:**

Medical magnetic tape recorder

**Classification:**

Class II, 21 CFR§870.2800, Recorder, Magnetic Tape, Medical

**Product Code:**

DSH, Medical magnetic tape recorder

### PREDICATE DEVICE(S) [807.92(a)(3)]

- Primary Predicate: iRhythm Technologies, Inc. ZIO® SkyRunner Electrocardiogram Monitoring Services (K143513) ("SkyRunner")
- Reference Devices:
    - GETEMED Medizin-und Informationstechnik AG, SEER 1000 (K130785)
    - Signalife, Inc., Signalife Fidelity 200 Cardiac Event Recorder (K071228)

## DEVICE DESCRIPTION [807.92(a)(4)]

The Peerbridge Cor™ System is a family of products comprised of two models, the Peerbridge Cor™ XT ("Cor XT") and the Peerbridge Cor™ Event ("Cor Event"). The system is an ambulatory wearable ECG monitoring system designed to record and provide patient's electrocardiogram (ECG) data to the clinician.

The Peerbridge System consists of five components: (1) Wearable ECG Sensor with Bluetooth technology, (2) Adhesive Electrode (3) dedicated Handheld Transmitter Device, (4) Data Upload Fixture and Software that allow ECG data to be uploaded from the Wearable ECG Sensor to a PC and then to the Backend, and (5) Cloud-based Backend Data Management Module. The Wearable ECG sensor attaches to the patient's chest and records the patient's ECG continuously. This device can collect two (2) channels of ECG data continuously for up to seven (7) days. In addition, patients can report symptomatic events by pressing the Event Button on the Wearable ECG Sensor or by using the mobile application on the Handheld Transmitter when a symptom is experienced. The device generates ECG reports to be displayed on the clinician's interface.

The Peerbridge System Cor XT and Cor Event have identical functionalities and components while differing in post-data acquisition clinical workflow. These configurations are presented in Table 1 with their respective tests. Through the two configurations, the system supports three tests based on medical necessity determined by the prescribing clinician.

**Table 1- Peerbridge System Family Configurations**

| Peerbridge Cor XT | Peerbridge Cor Event |
|---|---|
| Test 1: 24 hours of Holter monitoring | Test 1: 24 hours of Holter monitoring |
| Test 2: Up to 7 days of Holter Monitoring | Test 3: Patient Activated Event with Surveillance |

To initiate a test, the clinician uses the Peerbridge Portal to enter the patient's profile and select the appropriate test (Test 1, Test 2, or Test 3).

## INDICATIONS FOR USE [807.92(a)(5)]

The Peerbridge Cor™ System family of products is intended to capture and transmit symptomatic events and continuous external electrocardiogram (ECG) information for 24 hours and up to 7 days (long term monitoring). The Peerbridge Cor™ System contains a continuous external electrocardiogram (ECG) recorder with a patient-activated events button. It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, fatigue, or anxiety. The reported ECG metrics supports 2-channel ECG analysis on a beat-by-beat basis, heart rate measurement and rhythm analysis by FDA cleared algorithms. The report generated does not contain diagnostic interpretation; the report is provided for review by intended users to render a diagnosis based on their clinical judgment and experience.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]**

The Peerbridge System and the SkyRunner predicate device both capture, record, transmit, and analyze symptomatic events and continuous ECG recordings over an extended period in adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The Peerbridge System and the SkyRunner provide a report of the analyzed ECG data for the clinician to interpret. The reports for both systems are generated by FDA-cleared algorithms. Similar to the SkyRunner, the ECG data report is displayed in the clinician interface. Overall, the Peerbridge System is similar to the predicate device in terms of technological and safety characteristics and differences in technological characteristics have been analyzed and tested to ensure that there are no different questions of safety or effectiveness.

**SUBSTANTIAL EQUIVALENCE**

The Peerbridge System is substantially equivalent to the SkyRunner. The two devices have the same intended use and similar technological characteristics. Differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the Peerbridge System is substantially equivalent to the predicate device.

**PERFORMANCE DATA [807.92(b)]**

All necessary non-clinical testing was conducted on the Peerbridge System to support a determination of substantial equivalence to the predicate device.

**[807.92(b)(1)] Nonclinical Testing Summary:**

The nonclinical, bench testing included the following tests that were performed and passed:

- Software unit, integration, and system level testing
- Biocompatibility
- Electrical Safety and Electromagnetic Compatibility testing
- Defibrillation Safety testing
- ECG Wearable Sensor functional testing
- Wearability testing
- Summative human factors and usability testing

The collective results of the nonclinical testing demonstrate that the device meets its performance requirements and does not raise different questions of safety or effectiveness for measuring ECG or presenting information to the clinician when compared to the predicate device.

**[807.92(b)(2)] Clinical Testing Summary:**

Clinical testing is not provided in support of this premarket notification.

**CONCLUSIONS [807.92(b)(3)]**

In summary, the Peerbridge System and the SkyRunner have the same intended use and similar technological characteristics. Differences in the technological characteristics have been evaluated and supported with appropriate testing. Therefore, differences in technological characteristics do not raise different questions of safety or effectiveness.

**SUMMARY**

The Peerbridge Cor™ System is substantially equivalent to the predicate device.