U.S. FOOD & DRUG ADMINISTRATION

May 18, 2018

Braemar Corp.
David Norberg
Regulatory Affairs Representative
11481 Rupp Dr.
Burnsville, Minnesota 55337

Re: K981394
Trade/Device Name: Braemar ER700 Series Ambulatory ECG Event Monitor Models ER710, ER720
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH
Dated: July 15, 1998
Received: July 17, 1998

Dear David Norberg:

This letter corrects our substantially equivalent letter of September 28, 1998.

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K981394

DEVICE NAME: ER700 SERIES AECG EVENT MONITOR

INDICATIONS FOR USE:

TO RECORD INFREQUENT AND ELUSIVE ECG HEART ARRHYTHMIA DATA. ONCE THE EVENT IS RECORDED, PATIENTS TRANSMIT THE RECORDED ECG DATA OVER THE TELEPHONE. OR, AS AN ALTERNATE, THE ER700 SERIES ALLOWS THE ECG DATA TO BE TRANSFERRED DIRECTLY TO A HOST PC IF THE PATIENT RETURNS THE UNIT TO THE CLINIC.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981394

K981394

SEP 28 1998

SECTION 2. SUMMARY & CERTIFICATION

510(k) SUMMARY

- **Submitted By:** Braemar, Inc.
  11481 Rupp Drive
  Burnsville, MN 55337

- **Contact Person:** David Norberg

- **Device:** ER700 Series Cardiac Event Monitor
  Class: IIa

- **Description:** The ER700 Series is a family of patient-activated ambulatory electrocardiograph event recorders.

- **Intended Use:** To record infrequent and elusive ECG heart arrhythmia data. Once an event is recorded, patients transmit the recorded ECG data over the telephone. Or, as an alternative, the ER700 Series allows the ECG data to be transferred directly to a host PC if the patient returns the unit to the clinic.

- **Substantially Equivalent (SE) To:** Braemar ER300 Series
  510(k) # K923930

- **Comparison To The SE Device:**

Attribute	ER700 Series	ER300 Series
Liquid Crystal Display (LCD)	Yes	No
Looping memory	Yes	Yes
Memory type	Flash (non-volatile)	Solid State (volatile)
Number of ECG channels	One or two	One or two
Transtelephonic data transfer	Yes	Yes
Belt clip	Yes	Yes
Direct Data Transfer	Yes	No
Battery	Two AAA	One 9V