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

April 5, 2013

BioCare Corporation
C/O Shuchi Chang
4F, NO. 12, LANE 5, SEC. 2
NASHAN RD LUJHU TOWNSHIP
TAOYUAN COUNTY
CHINA, (TAIWAN) 33852

Re: K122307
Trade/Device Name: DIAVUE Prudential Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, NBW, JJX
Dated: February 25, 2013
Received: March 28, 2013

Dear Shuchi Chang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122307

DIAVUE Prudential Blood Glucose Monitoring System
The DIAVUE Prudential Blood Glucose Monitoring System is intended for use outside the body (*in vitro diagnostic use*) by people with diabetes at home to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples (from finger). This system is intended to be used by a single person and should not be shared. It should not be used for the diagnosis of or screening for diabetes, or testing on neonates.

DIAVUE Blood Glucose Test Strips
The DIAVUE Blood Glucose Test Strips are to be used with the DIAVUE Prudential Blood Glucose Meter; it measures glucose in capillary whole blood taken from a fingertip. It is for use outside of body (*in vitro diagnostic use*). It is intended for lay use by people with diabetes and should only be used by a single patient. This system should not be shared. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

DIAVUE Control Solutions
The DIAVUE Control Solutions are used with the DIAVUE Prudential Blood Glucose Meter and DIAVUE Blood Glucose Test Sreips to indicate appropriate user technique and to indicate that the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND / OR

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

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Katherine Serrano