



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Delbio Incorporation
c/o Nicky Pan
3F, No. 252, Shangying Road
Guishan Industrial Zone
Taoyuan County
China (Taiwan) 33341

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB - 8 2012

Re: k113343
Trade Name: DIACHECK SMART BLOOD GLUCOSE MONITORING SYSTEM,
DIACHECK SUPERIOR BLOOD GLUCOSE MONITORING
SYSTEM
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: December 9, 2011
Received: January 9, 2012

Dear Nicky Pan:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113343

Device Name: DiaCheck Smart Blood Glucose Monitoring System

Indications for Use:

DiaCheck Smart Blood Glucose Monitoring System:

The DiaCheck Smart Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples from the fingertips by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The DiaCheck Smart Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

DiaCheck Smart Blood Glucose Test Strips:

The DiaCheck Smart Blood Glucose Test Strips are for use with the DiaCheck Smart Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples from the fingertip. The Test Strip is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

DiaCheck Glucose Control Solution:

The DiaCheck Control solutions are intended for use with DiaCheck Blood Glucose Meter and DiaCheck Blood Glucose Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is being performed correctly.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113343

Indications for Use

510(k) Number (if known): K113343

Device Name: DiaCheck Superior Blood Glucose Monitoring System

Indications for Use:

DiaCheck Superior Blood Glucose Monitoring System:

The DiaCheck Superior Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples from the fingertips by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The DiaCheck Superior Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

DiaCheck Superior Blood Glucose Test Strip:

The DiaCheck Superior Blood Glucose Test Strips are for use with the DiaCheck Superior Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples from the fingertip. The Test Strip is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

DiaCheck Glucose Control Solution:

The DiaCheck Control solutions are intended for use with DiaCheck Blood Glucose Meter and DiaCheck Blood Glucose Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is being performed correctly.

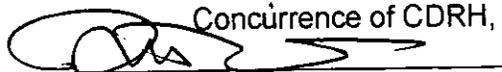
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113343