



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

DELBIO INCORPORATION
c/o Nicky Pan
252 Shangying Road
Guishan Industrial Zone
Taoyuan County
China (Taiwan) 33341

MAR 13 2012

Re: k103329
Trade Name: DiaTrue Plus 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: March 7, 2012
Received: March 7, 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).

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): K103329

Device Name: DiaTrue Plus Blood Glucose Monitoring System

Indications for Use:

DiaTrue Plus Blood Glucose Monitoring System:

The DiaTrue Plus Blood Glucose Monitoring System is an in vitro diagnostic medical device intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control and should not be shared. The device should not be used for screening or diagnosis of diabetes or for testing neonates.

DiaTrue Plus Blood Glucose Meter:

The DiaTrue Plus Blood Glucose Meter is intended to use for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body. It is indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control.

DiaTrue Plus Blood Glucose Test Strips:

The DiaTrue Plus Blood Glucose Test Strips are intended to use for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The Blood Glucose Test Strips must be used with the DiaTrue Plus Blood Glucose Meter. Testing is done outside the body. They are indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control.

DiaTrue Glucose Control solution:

For use with DiaTrue Blood Glucose Meter and DiaTrue Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Three levels of control solution are provided: Level I, Level II and Level III.

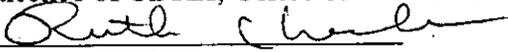
Prescription Use _____
(21 CFR 801 Subpart C)

AND/OR

Over-The-Counter Use X
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF 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) 103329