



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

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

Re: k120866

Trade/Device Name: DA01 Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, NBW, JJX,
Dated: October 3, 2012
Received: October 25, 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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 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/cdrh/industry/support/index.html>.

Sincerely yours,

Carol C. Benson 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): k120866

Device Name: DA01 Blood Glucose Monitoring System

Indications for Use:

DA01 Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood sample (from the finger and the palm). The alternate site testing can be only used during steady-state blood glucose monitoring. The DA01 Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The DA01 Blood Glucose Test Strips are used with the DA01 Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the finger and the palm.

The DA06 Glucose Control Solutions are for use with the DA01 Blood Glucose Test Strips and the DA01 Glucose Meter as a quality control check that the meter and test strip are working together properly, and that the test is performing correctly.

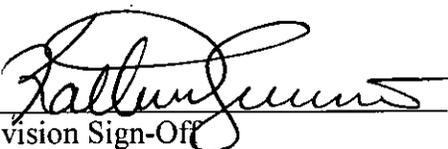
Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k120866