K093764

510(k) Summary (Per 21 CFR 807.92)

Updated on February 18, 2010

MAR - 2 2010

1. Submitter Information

Company name	Biotest Medical Corporation
Contact person	Maggie Chu, President
Address	No. 3-2, Chien-Kuo Road, TEPZ, Tantzu Taichung 427, Taiwan Republic of China
Phone	886-919099431
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2. Name of Device

Trade Name	SoloV2™ Blood Glucose Monitoring System
Common Name	Blood Glucose Meter
Classifications	NBW, Over the Counter Blood Glucose Test, 862.1345 CGA, Glucose Oxidase, 862.1345 Class II device

3. Predicate Device

Trade name	SuperCheck 1 Blood Glucose Monitoring System (SuperCheck 1), Model 6268
Common name	Blood Glucose Meter
Submitter	Biotest Medical Corporation
510(k) number	K091815

4. Device Description

The SoloV2™ Blood Glucose Monitoring System consists of a blood glucose meter, test strips, control solutions, lancing device, and commercially available lancets. The meter has a bilingual speaking feature that provides audible test results for users with low vision. The forearm may be used as an alternate site for capillary blood.

5. Intended Use

The SoloV2™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis or screening for diabetes mellitus, nor for use with neonates.

The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions.

This system contains a speaking function that provides audible test results for users with low vision.

6. Comparison to Predicate Device

Modifications to the cleared device include additional buttons for volume and language adjustment, additional pre-meal and post-meal Logging Flags, substitution of a USB connection for the previous RS232 cable, addition of an insufficient blood error message, and the removal of the test strip ejector mechanism. The size and shape of the device have also been modified to differentiate from the predicate. The SoloV2™ Blood Glucose Monitoring System has the same indented use and fundamental scientific technology as the previous version, the SuperCheck 1 Blood Glucose Monitoring System, Model 6268.

7. Performance Studies

Biotest Medical Corp. has conducted a risk analysis and has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements.

8. Conclusion

In summary, the modified SoloV2™ Blood Glucose Monitoring System has the same intended use and fundamental scientific technology as the previous version of the device, which received 510(k) clearance (K091815). Therefore, the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Biotest Medical Corp.
c/o Maggie Chu
No.3-2, Chien-Kuo Road, Tepz, Tantzu
Taichung, 427
China (Taiwan)

MAR - 2 2010

Re: k093764
Trade/Device Name: SoloV2™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: January 26, 2010
Received: February 1, 2010

Dear: Ms. Chu:

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

Enclosure

Indications for Use

510(k) Number (if known): k093764

Device Name: SoloV2™ Blood Glucose Monitoring System

Indications for Use:

The SoloV2™ Blood Glucose Monitoring System, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis or screening for diabetes mellitus, nor for use with neonates.

The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions.

This system contains a speaking function that provides audible test results for users with low vision.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (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

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