K091815

510(k) Summary

NOV 1 6 2009

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	866 4-2532-6668
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2. Name of Device

Trade Name	SuperCheck 1 Blood Glucose Monitoring System, Model 6268
Common Names	Blood Glucose Meter Blood Glucose Test Strips
Classifications	NBW, Over the Counter Blood Glucose Test, 862.1345 CGA, Glucose Oxidase, 862.1345 Class II device

3. Predicate Device

Trade/Proprietary	Prodigy Voice Blood Glucose Monitoring System
Common/Usual Name	Blood Glucose Meter Blood Glucose Test Strips
Submitter	Diagnostic Devices Inc.
510(k) Number	K073118

4. Device Description

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268 consists of a blood glucose meter, blood glucose test strips, control solutions, the lancing device, and lancets. The meter also comes with a speaking function that provides audible test results for users with low vision. The SuperCheck 1 Model 6268 allows the forearm to be used as an alternate site. User performance testing was conducted to support an over-the-counter indication.

5. Intended Use

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, 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. The SuperCheck 1 Blood Glucose Monitoring System is not intended for the diagnosis of 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

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, has equivalent technological characteristics and intended use as the Prodigy Voice Blood Glucose Monitoring System; however, the SuperCheck 1 has one alternate site at this time, the forearm.

7. Performance Studies

The performance of the SuperCheck 1 Blood Glucose Monitoring System, Model 6268 was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of the SuperCheck 1 system meets its intended use.

8. Conclusion

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268 demonstrates satisfactory performance, is suitable for its intended use, and 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 Corporation
c/o Diane Mandell Horwitz, Ph.D., RAC
Mandell Horwitz Consultants, LLC
2995 Steven Martin Dr.,
Fairfax, VA 22031

NOV 1 6 2009

Re: k091815
Trade/Device Name: SuperCheck 1 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: October 29, 2009
Received: November 2, 2009

Dear Ms. Mandell Horwitz

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 Form

510(k) Number: **K091815**

Device Name: **SuperCheck 1, Model 6268**

Indications for Use:

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, 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 of 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 IF NEEDED)

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

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K091815

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