K041107

JUN 1 8 2004

510 (k) Summary

1. Submitter Information

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Date Prepared	April 23th, 2004

2. Name of Device

Trade Names	TAIDOC CHECK Glucose Test System
Common Names/Descriptions	Blood Glucose Meter Blood Glucose Test Strips
Classification Names	Class II devices (21 CFR Section 862.1345, Glucose Test System)

3. Predicate Device

Trade/Proprietary Name:	GLUCOMETER ELITE Diabetes Care System
Common/Usual Name:	Blood Glucose Meter Blood Glucose Test Strips
Manufacturer	Bayer Diagnostics
510 (k) Number	K020208

4. Device Description

The TAIDOC CHECK glucose test system consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

5. Intended Use

The TAIDOC CHECK glucose test system is indicated for the quantitative measurement of glucose in fresh whole blood (capillary blood) for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

6. Comparison to Predicate Device

The TAIDOC CHECK glucose test system has equivalent technological characteristics as the GLUCOMETER ELITE Diabetes Care System (K020208). The TAIDOC CHECK glucose test system also has the same intended use as the GLUCOMETER ELITE Diabetes Care System.

7. Performance Studies

The performance of the TAIDOC CHECK glucose test system was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the TAIDOC CHECK glucose test system is suitable for its intended use.

8. Conclusion

The TAIDOC CHECK glucose test system demonstrates satisfactory performance and is suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 2004

Mr. Shu-Mei Wu
Project Manger
TaiDoc Technology Corporation
4F, NO. 88, Sec.1, Kwang-Fu Rd.
San-Chung, Taipei County
241 Taiwan

Re: k041107
Trade/Device Name: TAIDOC CHECK Blood Glucose Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: June 2, 2004
Received: June 2, 2004

Dear Mr. Wu:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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): K041107

Device Name: TAIDOC CHECK Blood Glucose Test System

Indications for Use:

The TAIDOC CHECK Blood Glucose test system is intended for use in the quantitative measurement of glucose in whole blood taken from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Carol C Benson

Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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