K082169

# 510 (k) Summary

DEC 0 4 2008



## 1. Submitter Information

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|---|---|
| Company name | TaiDoc Technology Corporation |
| Contact person | Yuhua Chen |
| Address | 6F, No. 127, Wugong 2nd Rd,<br>Wugu Township, Taipei County,<br>24888, Taiwan |
| Phone | (886-2) 6625-8188 |
| FAX | (886-2) 6625-0288 |
| E-mail | erica@taidoc.com |
| Date Prepared | July 30th, 2008 |

## 2. Name of Device

| | |
|---|---|
| Trade Names | TaiDoc Pro I Glucose Test Strip |
| Common Names/Descriptions | Blood Glucose Test System |
| Classification Names | Class II devices<br>(21 CFR Section 862.1345, Glucose Test System) |
| Product Code | NBW and LFR |

## 3. Predicate Device

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|---|---|
| Trade/Proprietary Name: | **Accu-ChcK Go Test System** |
| Common/Usual Name: | Blood Glucose test system |
| Manufacturer | Roche Diagnostics |
| 510 (k) Number | K040796 |

## 4. Device Description

The TaiDoc Pro I Glucose Test Strip is designed to quantitatively measure the concentration of glucose in whole blood. The test principle of the system utilize 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 Pro I Glucose Test Strip is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. The test strips are for use with Clever Chek TD-4222, Clever Chek TD-4230, Clever Chek TD-4231 Blood Glucose Meters and Clever Chek TD-3250C, and Fora Comfort 2 in 1 TD-3260 Blood Glucose plus Blood Pressure Monitors Only. 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.

Professionals may use the test strips to test capillary and venous blood samples, but lay user may not test venous blood samples.

## 6. Comparison to Predicate Device

TaiDoc Pro I Glucose Test Strip has equivalent technological characteristics and the similar intended use as the Accu-Chek Go Test System (K040796).

## 7. Performance Studies

The performance of TaiDoc Pro I Glucose Test Strip was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of this system meets its intended use.

## 8. Conclusion

TaiDoc Pro I Glucose Test Strip demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

TaiDoc Technology Corporation
c/o Yuhua Chen
Assistant Manager, Regulatory Affairs
6F, No. 127, Wugong 2nd Road
Wugu Township, Taipei County
China (Taiwan) 248

DEC 0 4 2008

Re: k082169
Trade/Device Name: TaiDoc Pro I Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: October 31, 2008
Received: November 3, 2008

Dear Yuhua Chen:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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: K082169

Device Name: TaiDoc Pro I Glucose Test Strip

Indication For Use:

The TaiDoc Pro I Glucose Test Strip is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. The test strips are for use with Clever Chek TD-4222, Clever Chek TD-4230, Clever Chek TD-4231 Blood Glucose Meters and Clever Chek TD-3250C, and Fora Comfort 2 in 1 TD-3260 Blood Glucose plus Blood Pressure Monitors Only.
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Prescription Use ___X___ (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)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082169