APR - 1 2010

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k093506

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
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Date Prepared	November 6th, 2009

2. Name of Device

Proprietary Names	CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Name	Class II devices (21 CFR Section 862.1345)
Product Code	NBW / CGA

3. Predicate Device

Trade/Proprietary Name:	FORA G30 Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Test System
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K090187

4. Device Description

The CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood. The test principle of 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 whole blood and control solutions.

5. Intended Use

The CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger and the following alternative sites: palm, forearm, upper arm, calf and thigh. 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.

The CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System cannot be used on neonates.

The alternative site testing in above systems can be used only during steady-state blood glucose conditions.

6. Comparison to Predicate Device

The intended use, test principle, and operating technology of CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System are all the same as the predicate device. The only difference between the predicate and proposed devices is in engineering modification.

This system uses amperometry for blood glucose measurement. The test is based on the measurement of electrical current generated by the reaction of glucose with reagents of the test strip.

7. Performance Studies

CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

The studies of software verification and validation testing, method comparison, and meter reliability test demonstrated that the performance of systems meets the intended use.

8. Conclusion

CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System demonstrates satisfactory performance and is suitable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

TaiDoc Technology Corporation
c/o Teling Hsu
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd Road, Wugu Township
Taipei County, China (Taiwan) 248

APR 0 1 2010

Re: k093506
Trade/Device Name: CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: February 26, 2010
Received: March 5, 2010

Dear Teling Hsu:

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 class II (Special Controls), 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).

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

510(k) Number (if known): k093506

Device Name:
CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System

Indications for Use:
The CLEVER CHOICE Auto-Code Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. 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.

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The alternative site testing in above systems can be used only during steady-state blood glucose conditions.

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

Carol C Benson

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(k)_____
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