Section 11. 510(k) Summary

MAR 2 6 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: K093941

1. Submitter's Identification:
   TaiDoc Technology Corporation
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   Correspondence:
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   Date of submission: December 18th, 2009

2. Device Name:
   Proprietary Name: CLEVER CHOICE Mini Blood Glucose Monitoring System
   Regulatory Information:
   A. Regulation Section: 21 CFR 862.1345 Glucose Test System
   B. Classification: Class II
   C. Product Code: CGA, Glucose Oxidase, Glucose
      NBW, System, Test, Blood Glucose, Over the Counter
   D. Panel: Clinical Chemistry (75)

3. Intended Use:

This system is intended for use outside the body (*in vitro* diagnostic use only). It is used for the quantitative measurement of glucose in fresh capillary whole blood samples taken from the finger and the following sites: the palm, forearm, upper arm, calf and thigh. It is intended for use by people with diabetes mellitus at home and by health care professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not for use on neonates.

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

4. Device Description:

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only CLEVER CHOICE Mini test strips and CLEVER CHOICE control solutions with the CLEVER CHOICE Mini Blood Glucose Monitoring System.

5. Substantial Equivalence Information:

A. Predicate device name:

FORA G30 Blood Glucose Monitoring System

B. Predicate K number: K090187

C. Comparison with predicate:

The modified CLEVER CHOICE Mini blood glucose monitoring system has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- A modification in the software of the glucose meter
- Modification in the physical appearance
- Engineering modifications
- Labeling change

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:
   CLEVER CHOICE Mini Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system performance demonstrated that the CLEVER CHOICE Mini blood glucose monitoring system and the currently marketed FORA G30 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the CLEVER CHOICE Mini blood glucose monitoring system is equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the CLEVER CHOICE Mini blood glucose monitoring system is substantially equivalent to the predicate FORA G30 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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c/o Ms. Debra Liang
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MAR 2 3 2010

Re: k093941
Trade/Device Name: CLEVER CHOICE Mini 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 12, 2010
Received: February 23, 2010

Dear Ms. Liang:

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

Section 8.

Indications for Use

510(k) Number: K093941

Device Name: CLEVER CHOICE Mini Blood Glucose Monitoring System

Indications for Use:

The CLEVER CHOICE Mini Blood Glucose Monitoring System 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. It is intended for use by people with diabetes mellitus at home and by health care professionals in clinical settings 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.

The alternative site testing in the above system 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 Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(k) K093941

Page 1 of 1