K042795

MAR 7 - 2005

510 (k) Summary

1. Submitter Information

Manufacturer	TaiDoc Technology Corporation
Contact person	Shu-Mei Wu
Address	4F, No. 88, Sec. 1, Kwang-Fu Rd., San-Chung, Taipei County, Taiwan
Phone	+886-2-66358080
FAX	+886-2-66355959
E-mail	shumei@taidoc.com.tw
Date Prepared	October 3 , 2004

2. Name of Device

Trade Names	CLEVER CHEK TD-3213™ Blood Glucose and Blood Pressure Measurement System
Common Names/Descriptions	Blood Glucose and Blood Pressure Measurement System Blood Glucose Test Strips
Classification Names	Class II devices 21 CFR Section 862.1345, Glucose Test System; 21 CFR Section 870.1130, Non-invasive Blood Pressure Measurement System

3. Predicate Device

Trade/Proprietary Name:	GLUCOMETER ELITE Diabetes Care System APM Blood Pressure Monitoring System, BP108A
Common/Usual Name:	Blood Glucose Meter; Non-invasive Blood Pressure Measurement System Blood Glucose Test Strips
Manufacturer	Bayer Diagnostics Asia Pacific Microsystems, Inc.
510 (k) Number	K020208; K040159

4. Device Description

The CLEVER CHEK TD-3213™ blood glucose and blood pressure measurement system consists of a meter with wrist cuff 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. Also, the system adopts the "oscillometric method" to as the measuring principle and provides the measurement of the systolic and diastolic blood pressure and heart rate of an individual by using a non-invasive technique in which as inflatable cuff is wrapped around the wrist. The pressure sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to determine the systolic and diastolic blood pressure and calculating pulse rate.

5. Intended Uses

The CLEVER CHEK TD-3213™ 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). The system also intended to use non-invasive measure the systolic and diastolic blood pressure and pulse rate or an adult individual, over age 16, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25"~7.75".

6. Comparison to Predicate Device

The CLEVER CHEK TD-3213™ system has equivalent technological characteristics as the GLUCOMETER ELITE Diabetes Care System (K020208) and APM Blood Pressure Monitoring System, BP108A (K040159). The CLEVER CHEK TD-3213™ system also has the same intended use as the GLUCOMETER ELITE Diabetes Care System and APM Blood Pressure Monitoring System, BP108A.

7. Performance Studies

The performance of the CLEVER CHEK TD-3213™ system was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the CLEVER CHEK TD-3213™ system is suitable for its intended use

8. Conclusions

The CLEVER CHEK TD-3213^{TM} system demonstrates satisfactory performance and is suitable for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 7 - 2005

Shu-Mei Wu, Ph.D.
Project Manager
Taidoc Technology Corporation
4F, 88, Sec.1, Kwang Fu Road
San Chung, Taipei
China (Taiwan) 241

Re: k042795
Trade/Device Name: Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX, DXN
Dated: January 12, 2005
Received: January 14, 2005

Dear Shu-Mei 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 (240)276-0484. 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/industry/support/index.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: K042795

Device Name: *Clever Chek TD-3213* Blood Glucose and Blood Pressure Measurement System

Indications For Use:

The *Clever Chek TD-3213* Blood Glucose and Blood Pressure Measurement System is intended for in vitro diagnostic use.

The system is intended to be used for the quantitative measurement of glucose in capillary whole blood from the fingertip. 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 not intended for use on neonates.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25"~7.75".

Prescription Use __X__ (AND/OR) Over-The-Counter Use ____X____
(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)

...ision Sign-Off)
...sion of Clinical ... ices
...(k) Number K042795