K070239

MAY 25 2007

510 (k) Summary

1. Submitter Information

Company name	Exir Pharmaceutical Company
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Date Prepared	Jan 18th, 2007

2. Name of Device

Trade Names	Maximed Exichek TD 4224 Blood glucose monitoring 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:	Clever Chek TD-4223 blood glucose monitoring system
Common/Usual Name:	Blood Glucose Meter Blood Glucose Test Strips
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K063212

4. Device Description

Maximed Exichek TD 4224 blood glucose monitoring 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

Maximed Exichek TD 4224 blood glucose monitoring system is indicated for the quantitative measurement of glucose in fresh capillary whole blood taken from the finger and the alternative sites 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 alternative site testing (the plam, the forearm, the upper arm, the calf and the thigh) in this system can be used only during steady-state blood glucose conditions.

6. Comparison to Predicate Device

Maximed Exichek TD 4224 blood glucose monitoring system has equivalent technological characteristics as the Clever Chek TD-4223 blood glucose monitoring system (K063212). Maximed Exichek TD 4224 blood glucose monitoring system also has the same intended use as the lever Chek TD-4223 blood glucose monitoring system

7. Performance Studies

The performance of Maximed Exichek TD 4224 blood glucose monitoring system 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

Maximed Exichek TD 4224 blood glucose monitoring system 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

Exir Pharmaceutical Company
c/o Erica Li
TaiDoc Technology Corporation
4F, No. 88, Sec. 1, Kwang-Fu Rd.,
San-Chung - Taipei County
Taiwan 241

MAY 25 2007

Re: k070239
Trade/Device Name: Maximed Exichek TD-4224 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: May 14, 2007
Received: May 18, 2007

Dear Ms. Li:

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:

Device Name: Maximed Exichek TD 4224 Blood glucose monitoring system

Indications for Use:

The Maximed Exichek TD 4224 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 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.

The alternative site testing in the Maximed Exichek TD 4224 Blood glucose monitoring 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 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
...on Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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