K062892

Eumed Biotechnology Co. Ltd.
3F, No.789, Boai St., Jubei City,
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# 510(K) Summary of Safety and Effectiveness

**(Per 21 CFR 807.92)**

JAN 2 2 2007

## General Information Establishment

- Manufacturer: **EUMED BIOTECHNOLOGY CO., LTD.**
- Address: 3F, NO. 789, BOAI ST.
  HSIN CHU HSIEN, China (Taiwan) 30265
- Registration Number: 3004379419
- Contact Person: Dr. Jen Ke-Min, **Official Correspondent**
  886-3-5208829 (Tel) 886-3-5209783 (Fax)
- Date Prepared: September 23, 2006

## Device

- **Proprietary Name:** EUKARE®
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II,

## Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to EUMED Biotechnology Co., Ltd. EUSURE® glucosure blood glucose monitoring system **(K040678)**

- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, EUKARE Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 15 seconds.

- **Intended Use:**

The EUKARE® glucose test strip is intended to measure the glucose in whole blood with the EUKARE® glucose meter. It is suitable for a person with diabetes to monitor their blood glucose at home by themselves. The system can also be used at clinical sites by nurses or professional people to test patient's glucose level in whole blood.

⚠ *1UTION: The measurement of glucose in whole blood can be taken from the finger only, and this is not for neonatal use.*

- **Synopsis of Test Methods and Results**

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

- **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to EUMED Biotechnology Co., Ltd., EUSURE® glucosure blood glucose monitoring system **(K040678).** Both of our devices (predicate device and subject device) use the same strip and have the same working principle and technologies. The differences are vision dimensions of the meter unit, weight and memory storage. There are no safety and effectiveness aspects arising from the subject device. They are substantially equivalent.

Ke-Min Jen, Dr.
Official Correspondent for
EUMED BIOTECHNOLOGY CO., LTD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ke-Min Jen
Eumed Biotechnology Co., Ltd.
3F, No. 789, Boai Street
Jubei City,
Hsinchu County, Taiwan 30265, R.O.C.

JAN 2 2 2007

Re: k062892
Trade/Device Name: EUKARE Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Blood Glucose Test System-Over the counter
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: December 3, 2006
Received: December 7, 2006

Dear Dr. Jen:

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

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# Indications for Use

510 (K) Number: **K062892**

Device Name: *EUKARE Blood Glucose Monitoring System*

Indications for Use:

The EUKARE Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body ( in vitro diagnostic use). It is indicated for use at home ( over the counter [OTC] ) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

⚠ *CAUTION: The measurement of glucose in whole blood can be taken from the finger only, and this is not for neonatal use.*

Prescription Use _____ AND/OR Over-The-Counter Use √

(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)

Division Sign-Off



Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062892

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# Indications for Use

510 (K) Number: **K062892**

Device Name: *EUKARE Blood Glucose Test Strips*

Indications for Use:

The EUKARE Blood Glucose Test Strips are intended to measure the glucose levels in whole blood with the EUKARE® / EUSURE® Blood Glucose Monitoring System. It is suitable for persons with diabetes to monitor their blood glucose levels at home by themselves. The system can also be used at clinical sites by health care professionals to test the blood glucose levels of patients.

⚠ *CAUTION: The EUKARE Blood Glucose Test Strips for use with EUKARE® / EUSURE® Blood Glucose Monitoring System only.*

Prescription Use ____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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# Indications for Use

510 (K) Number: **K062892**

Device Name: *EUKARE Blood Glucose Control Solution*

Indications for Use:

The EUKARE Blood Glucose Control Solution level I, level II, and level III are used as quality control material to verify the accuracy of the EUKARE® / EUSURE® Blood Glucose Monitoring System. If you are not sure about the strip quality or the previous storage condition, you are recommended to perform a quality control check. The control test results should always fall within the designed range listed on the box in use.

⚠ *CAUTION: The EUKARE Blood Glucose Control Solution for use with EUKARE® / EUSURE® Blood Glucose Monitoring System only.*

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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