K040678

JUL 1 4 2004

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **EUMED BIOTECHNOLOGY CO., LTD.**
- Address: 3F, NO. 789, BOAI ST.
  HSIN CHU HSIEN, China (Taiwan) 302
- Registration Number: 3004379419
- Contact Person: Dr. Ke-Min Jen
  Official Correspondent
  886-3-5208829 (Tel)
  886-3-5209783 (Fax)
- Date Prepared: March 11, 2004

Device

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

2.2. Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to Apex Biotechnology Corp. -- glucosure blood glucose monitoring system (K002621)

- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, ENSURE 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:**

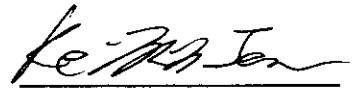
  The EUSURE® glucose test strip is intended to measure the glucose in whole blood with the EUSURE® glucose meter. It is suitable for a person with diabetes to monitor their blood glucose at home by themselves. The system can also be used at clinical sites by nurses or professional people to test patient's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

- **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 Apex Biotechnology Corp. -- glucosure blood glucose monitoring system (K002621). Both of them have the same working principle and technologies. The differences are electric voltage, dimensions of the unit and strip, weight. 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

JUL 1 4 2004

Mr. Ke-Min Jen
Official Correspondent
Eumed Biotechnology Co., Ltd.
3F, NO. 789, Boai St.
Hsin Chu Hsien, China (Taiwan) 302

Re: k040678
Trade/Device Name: EUSURE® 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: July 2, 2004
Received: July 9, 2004

Dear Mr. 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 (301) 594-3084. 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/dsma/dsmamain.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: **K040678**

Device Name: **EUSURE blood glucose monitoring system**

Indications For Use:

The EUSURE Blood Glucose Monitoring System is designed to measure the blood glucose levels in capillary whole blood. The system is suitable for diabetic patients 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. The test range is from 30 mg/dL to 600 mg/dL (1.67 – 3.33 mmol/L).

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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040678