K052818

JUN 16 2006

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **TYSON BIORESEARCH, INC.**
- Address: 5F, No. 22, Ke Tung Rd., Science Based Industrial Park, Chun-Nan, Miao-Li County, 350, Taiwan
- Registration Number: 3003132490
- Contact Person: Dr. Jen, Ke-Min
  Consultant
  886-3-5208829 (Tel)
  886-3-5209783 (Fax)
- Date Submitted: September 28, 2005

Device

- **Proprietary Name:** *EZ SMART-168 Blood Glucose Monitoring System*
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, Class II,

2.2. Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to VIP International Wholesalers, Corp. -- *EZ SMART Blood Glucose Monitoring System* (**K040848**).

- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, *EZ SMART-168 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 **10** seconds, and **28** blood glucose result memory.

- **Intended Use:**

The *EZ SMART-168 Blood Glucose Test Strips* are used with the *EZ SMART-168 Meter* to measure Glucose in whole blood. The *EZ SMART-168 Test Strips* are for testing outside the body (in vitro diagnostic use). The *EZ SMART-168 Blood Glucose Monitoring System* is intended for use in the home and in the professional settings to monitor blood glucose levels for better glucose level control among diabetics.

- **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 the predicate device VIP International Wholesalers, Corp. -- *EZ SMART Blood Glucose Monitoring System* (**K040848**). Both of them have the same working principle and technologies. The EZ Smart-168 Test Strip is identical to the EZ Smart Test Strip. **Only the meter coding method and memory size changes for more convenient operation of the EZ Smart Blood Glucose Monitoring System.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tyson Bioresearch Inc.
c/o Nathan A. Beaver, Esq.
Foley and Lardner
3000 K Street NW
Suite 500
Washington DC 20007

JUN 16 2006

Re: k052818
Trade/Device Name: EZ Smart-168 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: April 7, 2006
Received: April 11, 2006

Dear Mr. Beaver:

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.

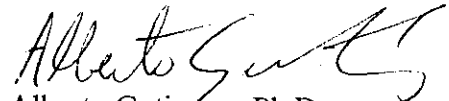
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



Alberto Gutierrez, Ph.D.
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: K052818

Device Name: EZ Smart-168 Blood Glucose Monitoring System

Indications For Use:

The *EZ Smart-168* Blood Glucose Test Strips are used with the *EZ Smart-168* Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood obtained from the fingertip. The *EZ Smart-168* Test Strips are for testing outside the body (*in vitro* diagnostic use). The *EZ Smart-168* Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels in persons with diabetes.

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)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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