K040848

AUG 11 2004

510(k) Summary

for

***EZ Smart* Blood Glucose Monitoring System**

1. DATE PREPARED

March 29, 2004

2. SPONSOR INFORMATION

Address

VIP International Wholesalers, Corp.
1860 Clove Road
Staten Island, NY 10304

Contact Person: George P. Drogaris, MS R.Ph.

(800) 566-3480 (telephone)
(718) 390-0473 (facsimile)

Outside Regulatory Counsel

Gray Cary Ware & Freidenrich LLP
1625 Massachusetts Ave., NW
Suite 300
Washington, DC 20036

Contact Person: David L. Rosen, B.S. Pharm., J.D.

(202) 238-7749 (telephone)
(202) 238-7701 (facsimile)

3. DEVICE NAME

Proprietary Name: *EZ Smart* Blood Glucose Monitoring System

Common/Usual Name: Blood Glucose Monitoring System

Classification Name: Glucose Test System (per 21 C.F.R § 862.1345 (2003))

4. DEVICE DESCRIPTION AND INTENDED USE

The *EZ* Smart Blood Glucose Test Strips are used with the *EZ* Smart Blood Glucose Meter to measure glucose (sugar) in whole blood. The *EZ* Smart Test Strips are for testing outside the body (*in vitro* diagnostic use). The *EZ* Smart Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

5. PREDICATE DEVICE

1. Predicate device name
   Bayer Elite with the Elite Test Strips

2. Predicate K Number
   K964630 (Bayer Elite)
   K991242 (Bayer Elite Test Strips)

3. Substantial Equivalence Comparison

Item	**Predicate Device** **Bayer ELITE (K964630)**	**Proposed Device** ***EZ Smart***
Similarities	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600mg/dL.	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600mg/dL.

Differences	ELITE	*EZ Smart*
	1. Size: 97.8 x 56 x 14.5 mm 2. Measuring time: 30 seconds	1. Size: 94 x 49 x 17 mm. 2. Measuring time: 10 seconds.

6. PERFORMANCE CHARACTERISTIC SUMMARY

An evaluation of the *EZ Smart* was conducted under various conditions including temperature effects, hematocrit levels, sensitivity and linearity, and presence of interferences. The results of the evaluation demonstrate that the *EZ Smart* is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 2004

VIP International Wholesalers, Corp.
c/o David Rosen
1625 Massachusetts Avenue NW
Suite 300
Washington, DC 20036-2247

Re: k040848
Trade/Device Name: EZ Smart Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: July 16, 2004
Received: July16, 2004

Dear Mr. Rosen:

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: K040848

Device Name: EZ Smart Blood Glucose Monitoring System

Indications For Use:

The EZ Smart Blood Glucose Test Strips are uses with the EZ Smart Meter to measure Glucose (sugar) in whole blood. The EZ Smart Test strips are for testing outside the body (in vitro diagnostic use). The EZ Smart 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.

George P. Lungu R.Ph. M.S.

Prescription Use ~~No~~ ✓ (AND/OR) Over-The-Counter Use ✓ yes
(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) K040848