K091765

VISGENEER INC.
3F.-2, No.83, Sec.2, Gongdao 5th Rd., Hsinchu City 300, Taiwan
Tel: 886-3-5160111 Fax: 886-5160161

JAN 19 2010

Section III. Summary

This Summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of (Per 21 CFR 807.92)

2.1 General Information Establishment

- Manufacturer: VISGENEER, INC.
- Registration Number : 3005644014
- Address : 3F.-2, No.83, Sec.2, Gongdao 5th Rd., Hsinchu City 300, Taiwan
- Phone : 886-3-5160111 Ext.3101
- Fax : 886-3-5160161
- Contact Person: Evonne Chen
- Date Prepared : April 1st , 2009

2.2 Name of Device

- Trade Name: eB*carryon* Blood Glucose Monitoring System
- Common Name: Blood Glucose Monitoring System
- Classification Name: SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II,

2.3 Predicate Device :

Claim of Substantial Equivalence (SE) is eBsensor Blood Glucose Monitoring System, eB-G. (K062555)

2.4 Description of Device :

Based on an electrochemical biosensor technology and the principle of capillary action, eB*carryon* 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 10 seconds.

VISGENEER INC.
3F.-2, No.83, Sec.2, Gongdao 5th Rd., Hsinchu City 300, Taiwan
Tel: 886-3-5160111 Fax: 886-5160161

2.5 Intended Use:

The **eB*carryon* Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in fresh capillary whole blood **from the finger.** The **eB*carryon* Blood Glucose Monitoring System** is not intended for the diagnosis of or screening for diabetes mellitus and is not for use on neonates. 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.

2.6 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.

2.7 Substantial Equivalence (SE):

A claim of substantial equivalence is made to Visgeneer INC. - eBsensor Blood Glucose Monitoring System, eB-G (K062555). Both of them have the same working principle and technologies. The differences are electric voltage, Meter Dimension of meter, Memory Storage, and weight. There are no safety and effectiveness aspects arising from the subject device. They are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Visgeneer, Inc.
c/o Ms. Evonne Chen
Supervisor of Control Quality Dept.
3F-2, No.83, Sec.2, Gongdao 5th Road,
Hsinchu City
Taiwan 30070

JAN 19 2010

Re: k091765
Trade name: eBcarryon Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: December 22, 2009
Received: December 22, 2009

Dear Ms. Chen:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

VISGENEER INC.
3F.-2, No.83, Sec.2, Gongdao 5th Rd., Hsinchu City 300, Taiwan
Tel: 886-3-5160111 Fax: 886-5160161

Indications for Use

510 (K) Number (If Known): K091765

Device Name: eB*carryon* Blood Glucose Monitoring System

Indications for Use:

The **eB*carryon* Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in fresh capillary whole blood **from the finger**. The **eB*carryon* Blood Glucose Monitoring System** is not intended for the diagnosis of or screening for diabetes mellitus and is not for use on neonates. 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.

Prescription Use V and/or Over the Counter Use V

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

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

...on Sign-Off

...ce of In Vitro Diagnostic Device
...uation and Safety

K091765