NOV 26 1999

K991850

510(k) Summary

1) Submitter's Name Address, contact

BioSafe Diagnostic Corporation
300 Knightsbridge Parkway, Suite 320
Lincolnshire, IL

Phone: (847) 821-7300
FAX: (847) 821-7400

Contact Person: Steven Tyrrell
BioSafe Laboratories
(773) 693-0400, x222

Date Prepared: May 28, 1999

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2) Device Name

Proprietary Name: Safe At Home Test Kit for Monitoring Hemoglobin A1c

Common Name: Self-monitoring Glycohemoglobin Blood Collection Kit

Classification Name: Glycosylated Hemoglobin Assay (21 CFR 864.7470)

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3) Predicate Device

EZCHEK/HBA Blood Collection Kit by Flexsite Diagnostics (#K971919), currently marketed by Becton Dickinson as the *BD A1c At Home Test™*

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4) Device Description

The device is a kit containing the materials necessary to collect a whole blood sample on a filter paper card and return the card by mail to the laboratory for determination of hemoglobin A1c. The kit comprises of a filter paper card in a resealable shipping bag containing a desiccant pouch, alcohol prep pad, disposable lancets, bandage strip, instruction booklet, a return envelope, and a patient test authorization form.

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5) Intended Use

The *Safe At Home Test Kit for Monitoring Hemoglobin A1c* is intended for home-use or office-use for collection and qualitative determination of hemoglobin A1c in dried whole blood. The product will be marketed over-the-counter.

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510(k) Summary, *continued*

6) Comparison to predicate device

The *Safe At Home Test Kit for Monitoring Hemoglobin A1c* has essentially the same intended use, technological characteristics and components as the predicate device. The components are the same except that the Flexsite Diagnostic's predicate device (*BD A1c At Home Test™*) does not include an alcohol preparation pad for pre-cleaning the patient's finger or a bandage strip. The kits differ also in that the blood collection spot paper in the Flexsite device is attached to the Test Request Form whereas these two components are separate in the BioSafe device. The use of this kit affects only the sample collection stage of the testing procedure.

7) Performance Studies

Performance studies were conducted on blood samples collected by both a trained health care professional and the lay user at three different geographical sites. A corresponding venous blood sample was collected by the health care professional in order to compare whole blood sample results to those obtained from dried blood samples collected on the *Safe At Home Kit for Monitoring Hemoglobin A1c*. Patients were instructed to self-collect their own capillary blood samples within 24 hours after leaving the collection site. All samples collected were mailed directly back to BioSafe Laboratories for determination of percent hemoglobin A1c.

Performance characteristics studied included precision and correlation. In addition, the *Safe at Home Test Kit for Monitoring Hemoglobin A1c* was evaluated for reagent and sample stability when exposed to abusive conditions. Study participants were requested to complete and return questionnaires regarding the kit's ease of use.

9) Test Summary

The evaluation studies provided evidence that results obtained using blood samples from untrained lay users correlate well with whole blood samples and capillary blood samples collected by trained health care professionals.

Study subjects indicated that the kit is acceptable as designed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 1999

Mr. Steven P. Tyrrell
Vice President, Director Research and Development
BioSafe Diagnostics Corporation
300 Knightsbridge Parkway
Suite 320
Lincolnshire, Illinois 60069

Re: K991850
Trade Name: Safe At Home Test Kit for Monitoring Hemoglobin Alc
Regulatory Class: II
Product Code: LCP
Dated: September 2, 1999
Received: September 7, 1999

Dear Mr. Tyrrell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K991850

Device Name: _____

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C. Indications for Use Statement

The Safe at-Home Test Kit for Hemoglobin A1c is intended as a home-use or office-use device for collection of capillary blood for *in vitro* diagnostic quantitative determination of hemoglobin A1c (glycosylated hemoglobin). The device will be used for monitoring long-term glucose control in people with diabetes. This kit is not indicated for the diagnosis of diabetes mellitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991850

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)