

K971919

SE 9-5-97

FLEXSITE DIAGNOSTICS, INC.

510(K) SUMMARY

May 21, 1997

SUBMITTER: FLEXSITE DIAGNOSTICS, INC.
3543 SW CORPORATE PARKWAY
PALM CITY, FL 34990

PHONE: 561 221-8893
FAX: 561 221-9671

CONTACT PERSON: Robert Ray
FLEXSITE DIAGNOSTICS, INC.
PHONE: 561 221-8893
FAX: 561 221-9671

TRADE NAME: EZCHEK™/HbA_{1c} Sample Collection Kit

COMMON NAME: Self-monitoring glycohemoglobin (hemoglobin A_{1c})
capillary blood collection kit.

CLASSIFICATION NAME: Glycosylated Hemoglobin Assay
(21C.F.R. 864.7470)

PREDICATE DEVICE: Self-Assure®/GHb; K861697/A.

DESCRIPTION: The device is a kit containing the materials required to collect a capillary blood sample from a finger-stick on a piece of filter paper and mail it to a laboratory for determination of its hemoglobin A_{1c} %. The kit contains a lancet, an alcohol wipe, a test request form with filter paper, a biohazard bag, a return envelope and a label for returning a result to the patient and/or his/her doctor.

INTENDED USE: The device is intended for at-home or in-office use to collect a sample for hemoglobin A_{1c} determination. The product will be marketed over-the-counter.

SUMMARY OF TECHNOLOGICAL SIMILARITIES AND DIFFERENCES:

SIMILARITIES: The key components of the kit are functionally identical to those in the Self-Assure kit.

- DIFFERENCES:**
1. The method of analysis of glycohemoglobin has changed from affinity chromatography to an antibody method from another commercial source. This method is FDA cleared.
 2. The filter paper treatment has been changed to be compatible with the new antibody method. The new treatment is with a standard chemical in common use in clinical labs.
 3. The name of the product has been changed.

NONCLINICAL PERFORMANCE DATA: The principal difference as noted in above is the method of analysis. The new antibody based method, which as cleared uses whole blood or whole blood hemolysate samples, was shown to give accurate results when using blood spots collected on filter paper as judged from the following correlation data: $y = 1.03x - 0.13$; $r = 0.988$; $n = 53$. The precision of measuring blood spots was 2.9% within run at 6.7% HbA_{1c}. Total precision over a 20 day study was 3.3 % at 6.7% HbA_{1c}. The stability of blood spots at temperature extremes was shown to be compatible with expected transport conditions (up to 115°F and to three freeze-thaw cycles).

CLINICAL PERFORMANCE DATA: Kits were evaluated in three sites to confirm the ease of use by medical professionals in an office setting. Results were also correlated to whole blood hemolysate tests as an additional confirmation of the validity of collection on filter paper. Correlation was $Y = 0.999x + 0.06$; $r = 0.978$; $n = 56$. Patients given the kit to take home gathered samples and mailed them to the laboratory. These results also correlated very well ($y = 0.983x + 0.37$; $r = 0.956$; $n = 43$) to whole blood hemolysate results. Patients filled out questionnaires regarding the ease of use etc. Their comments indicated that the kit is acceptable as designed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 1997

Donald R. Stone
Flexsite Diagnostics, Inc.
C/O McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K971919
EZCHEK™/HBA Sample Collection Kit
Regulatory Class: II
Product Code: LCP
Dated: August 15, 1997
Received: August 15, 1997

Dear Mr. Stone:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

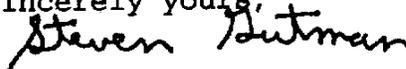
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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: K971919

Device Name: EZCHEK™/HbA_{1c} (Glycohemoglobin Sample Collection Kit)

Indications for Use:

For over-the-counter at home or doctor's office use to obtain a finger stick whole blood sample for laboratory testing to monitor long-term (4-8 weeks) blood sugar control in diabetes. Test results should be evaluated together with a personal doctor. This product is not indicated for the diagnosis of diabetes mellitus.


(Division of)
Division of Clinical Laboratory Devices
510(k) Number K971919

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use