K983172

NOV 30 1998

Summary of Safety and Effectiveness

Submitter: Diabetes Technologies, Inc.
216 west Jackson Street
Thomasville, GA 31792
Phone: 912-227-1752
FAX: 912-227-0827

Contact Person: Arthur G. Williams
President

Date Prepared: September 1, 1998

Product Trade Name: Accu-Base Hemoglobin A_{1c} Sample Collection Kit.

Common Name; Glycohemoglobin (HbA_{1c}) Test Kit

Classification name: Glycated Hemoglobin Assay (21 C.F.R. 864.7470 and 81LCP

Predicate Device:
1. A1c-CHEK (HbA1c-1), K973365, Express Med, Inc.,
2. EZCHEK™/HbA_{1c} Sample Collection Kit, FLEXSITE Diagnostics, Inc., K971919
3. Self Assure/GHb, Awareness Technology, Inc., K861697A
4. Diamat Glycosylated Hemoglobin analyzer Reagent System, Bio-Rad laboratories., K851636

The Accu-Base Hemoglobin A_{1c} Sample Collection Kit is packaged in two sizes or configurations designed for professional use. One kit is designed for patient take home use and is available in a one (1), two (2) and three (3) test kit configuration. The other, the (Point of Care Kit) is designed with ten (10) tests for in-office use. The Point of Care Kit is ideal for the physician's office, clinic, small hospital and/or diabetes clinic and/or laboratory.

The at-home kit is designed to be used by qualified patients (physician discretion) in the privacy and convenience of their home. The at-home kit is designed to facilitate the collection, preparation, storage and transport of capillary (finger-stick) hemoglobin A_{1c} patient samples for laboratory analysis while providing empowerment and self-management training for the patient. The kit contains sufficient supplies and materials to collect either 1, 2 or 3 individual HbA_{1c} patient samples including:

1 durable self-contained shipper with built in labeled workstation.
1, 2 or 3 vials of (1 ml of hemolysis reagent),
1 capillary tube holder,
2-5 Na Heparinized 5µl capillary tubes (in labeled capillary dispenser) depending on the actual number of tests in the kit.
1-3 biohazard specimen bags with absorbent pads for airtight sample transport.
1-3 positive patient ID laboratory forms with peel off ID labels that are attached to the hemolysis vials (sample preparation vials).
1-3 sample mailers (pre-addressed/postage paid) to designated laboratory.

Kit contents continued:

1 patient size HbA_{1c} longitudinal tracking log.
Product insert (Information & Instructions Booklet)
1 Mean Blood Glucose Monitoring Journal
Toll free (24 hour) technical assistance line 888-872-2443

Note: Once the sample is collected and prepared, the Red Blood Cells (sample) Are hemolyzed, Schiff base removed and the sample is preserved for analysis and/or freezing for future analysis.

In both cases, the finger, ear lobe or heal (pediatric patient/infants), is pierced (lanced) using a traditional sterile, disposable lancet device (SafeLet). The patient and/or care provider is instructed to lance the finger, wipe away the first drop, milk the finger toward the puncture site and collect the second drop of blood. A capillary tube is attached to a capillary tube and is filled with whole blood from the finger, the tube is filled from end to end (approximately 5µl of blood). The capillary tube is than wiped of any excess blood and placed in the open vial containing the hemolysis reagent.

The vial is closed tightly and gently rotated to mix the sample with the hemolysis reagent (ensuring that all of the blood has transferred from the capillary tube to the surrounding reagent. (no blood or RED line will be visible in the tube once the vial has been properly mixed. The solution will be a heterogeneous light to dark pink color). The vial is labeled using the peel off label provided on the Patient Identification Form (sequenced number specific to that sample that are non-repeating numbers).

The lab form ID number corresponds to the vial number for positive ID at the laboratory. The labeled and mixed sample is placed in a biohazard bag, which also contains instructions for use to ensure proper sample processing. The bag is sealed using self-adhesive tape to ensure an airtight seal of the specimen during transport. The sealed biohazard bag is then placed in the sample mailer along with the lab ID form and closed with sealing tape to ensure safe undisturbed transport of the sample to the designated laboratory.

The patient's sample can be dropped in the mail as soon as collected and prepared or placed in the refrigerator overnight if the sample is not going to be mailed the same day. The sample is stable for up to 14 days at room temperature and up to 21 days at refrigerated temperatures. The sample is considered pre-treated and incubated when it arrives in the testing laboratory and can be immediately analyzed without any further treatment, dilution, elution or preparation. The lab verifies the patient name and ID number and performs the test using an automated Bio-Rad Laboratories HPLC instrument such as the MDMD™, Variant™ or Diamat™ system).

It is further intended that the copies of the patient's results may be sent to the patient, physician and other entities as directed and approved by the physician and patient including: insurance and managed care companies to whom these individuals are current members as part of a more comprehensive outcomes measurement program for diabetes.

Ordering of the kit for patient at-home use is determined by the physician *qualifying* the patient and/or care provided as to the individuals motivation to participate in self-management, their literacy level to follow written and visual instructions, visual impairment assessment (sight level), mental impairment assessment and physical impairment as well as their dexterity to complete the required collection steps.

Intended use of the kit includes HbA_{1c} samples from children (pediatrics) ages one and older (special consideration to hemoglobin F) is determined using HPLC during the first year of life. While the kit is *designed for use in children*, it is not recommended to be collected by children and therefore a KEEK OUT OF REACH OF CHILDREN label is posted on the kit.

The level of sample collection complexity can and should be compared to the use of a glucose meted by individuals with diabetes that are currently using and comfortable with using a SMBG Blood Glucose Meter.

In the case where a child, visually, mentally impaired or physically challenged individual is to have a sample collected at-home, a third person that has been trained and/or qualified on the use of the kit is responsible for assisting the patient with the sample collection. Easy to follow instruction and a toll free help line is available for these or any individual that requests assistance. In addition, the sample can be drawn (collected) by any health care professional, clinical laboratory, visiting nurse, and home health agency. Once the patient has been qualified to collect the sample at-home, follow-up kits can be automatically shipped to the patient as required (directed) by the physician.

To establish substantial equivalence to an existing (predicate device), and thus establish the Safety and Effectiveness of the Accu-Base Hemoglobin A_{1c} Sample Collection kit, capillary samples were first compared to the traditional venipuncture method in adults and children with diabetes using the same Bio-Rad Diamat reagent analytical system and method (HPLC venous to capillary comparison). The 48 patient precision and accuracy study was preformed at the Diabetes Research Institute at the University of Miami. As the data indicates excellent correlation was achieved (0.99218). An additional 100 patient Clinical Trial (including a field user evaluation) was preformed with patients from the Tulane Endocrine Clinic over a several month period. The results were considered very acceptable for both precision of home to lab collected samples as well as the *user feedback* as to their acceptance and perception of the kit. 90% of patient's preferred the at-home kit over venipuncture and the clinical data

revealed excellent correlation of Mean ± SD A1c was 8.1 ± 1.9 LAB and 8.3 ± 1.7 KIT (p=NS).

The analytical method used in the kit is the NIH reference method and can detect Hemoglobinopathies and abnormal RBC conditions such as anemia.

Additional feasibility clinical trials were conducted at the Park Nicollet Medical Center and The International Diabetes Center in Minneapolis that resulted in the clinical conclusion that the collection system is accurate, stable and simple to use. Their clinical results revealed "excellent agreement between the capillary and venous HbA_{1c} values, (capillary 0.959, venous + 0.494, $R^2 = 98.7\%$).

The Point of Care (10 test kit), professional use kit is designed for low volume hospitals, clinical and large volume doctors offices. The kit includes sufficient supplies and materials to collect and process 10 samples. The kit includes patient chart size HbA_{1c} tracking logs, The kits contain all of the supplies found in the smaller kits contained in a larger storage kit with the same printed instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 30 1998

Arthur G. Williams
President
DIABETES TECHNOLOGIES, INC.
216 West Jackson Street
Thomasville, GA 31792

Re: K983172
Trade Name: Accu-Base Hemoglobin A1c Sample Collection Kit
Regulatory Class: II
Product Code: 81 LCP
Dated: September 1, 1998
Received: September 10, 1998

Dear Mr. Williams:

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.

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/dsma/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

Statement of Intended Use

510 (k) Number (if known) K 983172

Device Name: Accu-Base Hemoglobin A_{1c} Sample Collection Kit

Indications for Use: The intended use of the Accu-Base Hemoglobin A_{1c} Sample Collection Kit is for the determination of the relative percent (%) hemoglobin A_{1c} in human whole blood (capillary) samples, using high performance liquid chromatography (HPLC)as the analytical method.

The Accu-Base Hemoglobin A_{1c} Sample Collection Kit will be available to patients through Point of Care Offices and/or Centers, for the purpose of monitoring individual, long-term diabetes control as part of a comprehensive diabetes management & treatment program.

The Accu-Base Hemoglobin A_{1c} Sample Collection Kit does not replace daily blood glucose monitoring.

There are no known contraindications.
Keep out of reach of children.

The intended reporting path of the HbA_{1c} test results include direct reporting to the physician/health care professional responsible for the care of the individual for clinical interpretation including setting and interpreting specificHbA_{1c} target goals and test results. In addition the results may be reported to the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDHR, Office of Device Evaluation (ODE)

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

e.g., Home use by prescription.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k 983172