



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Arthur G. Williams
Applicant/Chief Scientific Officer
Diabetes Technologies, Inc.
216 West Jackson Street
Thomasville, Georgia 31792

JAN 29 2002

Re: k013465
Trade/Device Name: Accu-Base A_{1c} Test Kit
Regulation Number: 21 CFR § 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: II
Product Code: LCP
Dated: November 8, 2001
Received: November 15, 2001

Dear Mr. Williams:

This letter is to correct the letter sent on January 22, 2002, regarding the device name change from Accu-Base Hemoglobin A_{1c} Sample Collection Kit to Accu-Base A_{1c} Test Kit. 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

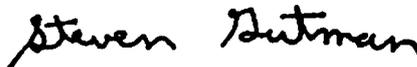
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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) (if known): K013465
 Trade/Device Name: AccuBase A_{1c} Test Kit
 Indications for Use: The intended use of the AccuBase A_{1c} Test Kit is for the determination of the relative percent (%) A_{1c} (glycohemoglobin) in human whole blood (capillary) samples, using high performance liquid chromatography (HPLC) as the analytical method.

The AccuBase A_{1c} Test Kit will be available to diabetes patients through physicians, pharmacies, diabetes supply and/or OTC distribution companies for the purpose of monitoring the average glucose concentration in the body over the past 30, 60 or 90 days including; a calculated Mean Blood Glucose (MBG) determination based on the DCCT MBG equation $(31.7 \times A_{1c} \% - 66.1) = \text{MBG mg/dl}$ as part of an comprehensive individual diabetes outcomes management, glycemic status assessment and treatment program.

The AccuBase A_{1c} Test Kit does not replace daily blood glucose monitoring.

While there are no known contraindications, it is well known that the existence of disturbed erythrocyte kinetics conditions (such as anemia) may result in a non-reportable test result due to too few Red Blood cells per volume of sample. A list of potential confounding factors are reported on the test result at time of reporting. Keep out of reach of children and pets.

The intended reporting path of the AccuBase A_{1c} test Kit test result include direct reporting to patients and/or a healthcare professional. Test results must be provided to a physician and/or healthcare professional for interpretation of specific A_{1c} values and setting of specific target A_{1c} goals.

Josephine Banta da
 (Division Sign-Off)
 Division of Clinical Laboratory Devices

510(k) Number K013465

(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