DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 15 1998

D. Alan Scantland
Commercial Development
Express-Med, Inc.
3592 Coporate Drive
Columbus, Ohio 43231-4978

Re: K973365
A_{1c} - Express
Regulatory Class: II
Product Code: LCP
Dated: April 8, 1998
Received: April 9, 1998

Dear Mr. Scantland:

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 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 (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

INDICATIONS FOR USE STATEMENT

The Office of Device Evaluation (ODE) has developed the attached optional form to assist them with instituting the requirement for all original 510(k)s received by ODE on or after 1/2/96.

The requirement is for all 510(k) submissions to have clearly defined "Indications for Use". These indications will be attached by ODE to any substantial equivalence (SE) letter to define what the device is cleared for.

No 510(k) submitted on or after 1/2/96 will be cleared for marketing by ODE without the inclusion of the indications for use information, which will be attached to an SE letter.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K973365

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

Indications For Use: We propose the following Indications for Use Statement.

The intended use of Express-Med's A_{1c}-EXPRESS is for the determination of percent of hemoglobin A_{1c} in human whole blood samples. Clinically, Express-Med's A_{1c} -EXPRESS is intended to be used as a measure of long-term glycemic control in patients with *diabetes mellitus*. This product will be available to patients through Point of Care offices.

Preferably, A_{1c}-EXPRESS should be used in conjunction with other diabetes management tools, including consultation with health care professionals, goal-setting, education, exercise, diet, and, when prescribed, medication.

A_{1c}-EXPRESS does not replace daily blood glucose monitoring.

There are no known contraindications.

The kit should be kept out of reach of children.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973365

Prescription Use OR ~~Over-The-Counter Use~~

(Per 21 CFR 801.109)

(Optional Format 1-2-96)