AUG 2 7 2003

BIO-RAD

Bio-Rad Laboratories

Diagnostics Group
4000 Alfred Nobel Drive
Hercules, California 94547
Telephone: 510 724-7000
Fax: 510 741-5824

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K031043.

Submitter:

Bio-Rad Laboratories, Inc.
Clinical Diagnostics Group
4000 Alfred Nobel Drive,
Hercules, California 94547
Phone: (510) 741-5309
FAX: (510) 741-6471

Contact Person:

Jackie Buckley
Regulatory Affairs Representative

Date of Summary Preparation:

March 31, 2003

Device Name:

D-10™ Hemoglobin A_{1c} Program

Classification Name:

Assay, Glycosylated Hemoglobin, 81LCP

Predicate Device:

VARIANT™ II Hemoglobin A_{1c} Program
K984268
Bio-Rad Laboratories, Inc.

Statement of Intended Use:

The Bio-Rad D-10 Hemoglobin A_{1c} Program is intended for the percent determination of hemoglobin A_{1c} in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The D-10 Hemoglobin A_{1c} is intended for use only with the Bio-Rad D-10 Hemoglobin Testing System.

For In Vitro Diagnostic Use.

Description of Device:

The D-10 Hemoglobin Testing System uses the principles of high performance liquid chromatography (HPLC). The D-10 Hemoglobin A_{1c} Program is based on chromatographic separation of Hemoglobin A_{1c} on a cation exchange cartridge.

Technical Characteristics Compared to Predicate:

D-10 and VARIANT II systems have the same technical characteristics that are summarized in the table below:

Characteristics	D-10 Hemoglobin A_{1c}	VARIANT II Hemoglobin A_{1c}
Analyte Measured: Reported	%A1c	%A1c
Intended Use	The Bio-Rad D10 Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC).	The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC).
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
Sample Type	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA)
Visible Detection	415 nm	415 nm
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).

Testing To Establish Substantial Equivalence:

Method correlation between D-10 Hemoglobin A_{1c} Program and VARIANT II Hemoglobin A_{1c} Program was evaluated with 40 anticoagulated whole blood samples ranging from 4.98% to 12.15% HbA1c. The results are presented in the following table:

Regression Method	n	r^2	Slope	Intercept
Least Squares	40	0.9945	0.9743	0.3078

Conclusion:

When considering the similarities of the intended use, general characteristics of the two assays, the use of the same technology and excellent correlation between the two methods, it can be concluded that the D-10 Hemoglobin A_{1c} Program and VARIANT II Hemoglobin A_{1c} Program are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 27 2003

Ms. Jackie Buckley
Regulatory Affairs Representative
Bio-Rad Laboratories, Inc.
Diagnostics Group
4000 Alfred Nobel Drive
Hercules, CA 94547

Re: k031043
Trade/Device Name: D-10 Hemoglobin A1c
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: July 25, 2003
Received: July 29, 2003

Dear Ms. Buckley:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K031043

Device Name: Bio-Rad D-10™ Hemoglobin A_{1c} Program

Indications for Use: The Bio-Rad D-10 Hemoglobin A_{1c} Program is intended for the percent determination of hemoglobin A_{1c} in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The D-10 Hemoglobin A_{1c} Program is intended for use only with the Bio-Rad D-10 Hemoglobin Testing System.

For In Vitro Diagnostic Use.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K031043

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptive Use ✓ OR Over-The-counter Use _____
(Per 21 CFR 801.109)