K984268

DEC 17 1998

510(k) Summary of Safety and Effectiveness

Submitter:	Bio-Rad Laboratories, Inc. 4000 Alfred Nobel Drive Hercules, California 94547 Phone: 1-510-741-6188 FAX: 1-510-741-6471
Contact Person:	Juliet Carrara Regulatory Affairs/Quality Assurance Manager
Date of Summary Preparation:	November 23, 1998
Device Name:	VARIANT™ II HbA1c Program
Classification Name:	Assay, Glycosylated Hemoglobin, 81 LCP
Predicate Device:	VARIANT™ HbA1c Program K926469 Bio-Rad Laboratories Hercules, CA 94547
Statement of Intended Use:	The VARIANT™ II Hemoglobin A_{1c} Program is intended for the determination of hemoglobin A_{1c} in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The VARIANT™ II Hemoglobin A_{1c} Program is intended for use only with the Bio-Rad VARIANT™ II Hemoglobin Testing System. For in vitro diagnostic use only.

Description of Device

The VARIANT™ II Hemoglobin A_{1c} Program is based on chromatographic separation of HbA_{1c} on a cation exchange cartridge. The analytical system of instrument and reagent kit provides a means of measuring Hemoglobin A1c, formed by the non-enzymatic attachment of circulating blood glucose to the N terminal valine of the β-chain of the hemoglobin molecule (HbAo). Attachment of glucose to hemoglobin is achieved in a two

step process. The first step is the formation of an unstable aldimine (Schiff base, labile, or pre-A1c), a reversible reaction between the carbonyl group of glucose and the N terminal valine of the β-chain of hemoglobin. The amount of Schiff base formed is directly proportional to the blood glucose concentration. The second step is the much slower and irreversible conversion of the Schiff base intermediate to the stable "ketoamine" product (Hemoglobin A1c). The percentage of Hemoglobin A1c in whole blood is dependent on the level of sustained blood glucose and indicative of mean blood glucose over the lifetime of red blood cells (≈ 120 days).

Testing To Establish Substantial Equivalence

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness, the VARIANT™ II HbA1c Program has been compared to the VARIANT™ HbA1c Program (K926469). A review of the intended use of each system shows them to be the same, in that, they both measure Hemoglobin A1c in a sample of whole blood using cation exchange high performance liquid chromatography.

Technical Characteristics Compared to Predicate

Both systems have the same technical characteristic as presented in the table below:

	VARIANT™ II HbA1c	**VARIANT™ HbA1c**
Separation Mechanism	Cation exchange chromatography	Cation exchange chromatography
Sample Preparation	Direct dilution of whole blood in aqueous medium	Direct dilution of whole blood in aqueous medium
Measurement Type	Quantitative area percent	Quantitative area percent
Use of Controls	Two levels of control per run	Two levels of control per run
Visible Detection Wavelength	415nm / 690nm	415nm / 690nm

The VARIANT™ II HbA1c Program has added front end automation and Clinical Data Management Software capabilities. The front end automation allows sampling from primary sample tubes. The predicate used a hemolysis reagent during sample preparation to remove Schiff base. The VARIANT™ II HbA1c Program separates Schiff base from HbA1c in the analysis step.

The performance of the VARIANT™ II HbA1c Program was evaluated for precision, measuring range, and accuracy. The precision studies were done using a modified protocol based on the NCCLS Evaluation protocol, Vol. 12, No 4, EP5-T2. Using this protocol, precision of the system was determined using a low, medium, and high patient whole blood sample. The Within-run %CV for the low was 1.51%, for the medium 1.93%, and for the high patient 1.04%. The Between run %CV for the low was 2.40%, for the medium 2.01%, and for the high patient 0.92%. Total precision was 4.10% for the low, 3.36% for the medium, and 2.00% for the high patient. The VARIANT™ II HbA1c Program meets the precision requirements of the National Glycohemoglobin Standardization Program (NGSP).

A correlation study, to determine accuracy of the VARIANT™ II HbA1c Program, was done against the VARIANT™ HbA1c Program. The study followed NCCLS Document EP9-T. The "r^2" for the correlation was 0.9885.

When considering the similarities of the intended use, general characteristics of the two assays, the use of the same technology and the excellent correlation between the two methods, it can be concluded that the VARIANT™ II HbA1c Program and the VARIANT™ HbA1c Program are substantially equivalent. Based on the establishment of substantial equivalence, the safety and effectiveness of the VARIANT™ II HbA1c Program is confirmed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 1998

Ms. Juliet Carrara
Manager, Regulatory Affairs
and Quality Assurance
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547-1803

Re: K984268
Trade Name: VARIANT II HbA1c Program
Regulatory Class: II
Product Code: LCP
Dated: November 23, 1998
Received: November 30, 1998

Dear Ms. Carrara:

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 Indications for Use

510(k) Number: K984268

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Indications for Use:

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The VARIANT™ II Hemoglobin A_{1c} Program is intended for use only with the Bio-Rad VARIANT™ II Hemoglobin Testing System.

For in vitro diagnostic use only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984268

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

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