Summary of Safety and Effectiveness

DEC - 1 2006

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: K 063400 .

Submitter:	Bio-Rad Laboratories, Inc. Clinical System Division 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:	Nov. 8, 2006
Device Name:	VARIANT™ II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System using Clinical Management System (CDM) 4.0
Classification Name:	HbA_{1c}: Assay, Glycosylated Hemoglobin [21CFR 864.7470 / Prod. Code LCP]
Predicate Devices:	VARIANT II TURBO Hemoglobin A1c Bio-Rad Laboratories, Inc. [K040872, April 15, 2004]

Intended Use:

The Bio-Rad VARIANT™ II TURBO 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 VARIANT II TURBO Hemoglobin A1c Program is intended for Professional Use Only. For In Vitro Diagnostic Use.

Indications for Use:

Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

New Device Description

The VARIANT II TURBO Hemoglobin Testing System uses the principles of high performance liquid chromatography (HPLC). The VARIANT II TURBO Hemoglobin A1c Program is based on chromatographic separation of Hemoglobin A1c on a cation exchange cartridge.

The new feature in this submission is the upgrade in CDM software. The current software (CDM 3.6T) requires Windows NT. This product is nearing the end of its lifecycle. CDM 4.0 software is needed to transfer the CDM software to Microsoft XP Operating System.

Technical Characteristics Compared to Predicate

The VARIANT™ II TURBO Hemoglobin A1c Program run on the VARIANT™ II TURBO Hemoglobin Testing System with CDM 4.0 has the same basic technical characteristics as the predicate VARIANT II TURBO Hemoglobin A1c Program (k) 040872. The technical characteristics between the two submissions are summarized in the following tables:

VARIANT™ II TURBOHemoglobin A1c (k)040872

Summary of Technological Characteristic Similarities in Comparison to Predicate Device		
Characteristics	**New Device:** **VARIANT II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System using CDM 4.0**	**Predicate Device: (k) 040872** **VARIANT II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System using CDM 3.6T**
Intended Use(s)	The VARIANT II TURBO Hemoglobin A1c 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 TURBO Hemoglobin A1c Program is intended for Professional Use Only. For In Vitro Diagnostic Use.	The VARIANT II TURBO Hemoglobin A1c 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 TURBO Hemoglobin A1c Program is intended for Professional Use Only. For In Vitro Diagnostic Use.
Indication(s) for Use	Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus.	Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus.
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
CDM Software version	4.0	3.6T
Microsoft software	Windows XP	Windows NT
Object Store version	6.0	4.0
Backup and Restore	Use Windows operation to write only data to CD-R	Used Easy CD writer Read/Write
Database Management	Delete data directly from database	Substitute database with a blank database

Testing To Establish Substantial Equivalence:

Accuracy:

VARIANT II TURBO Hemoglobin HbA1c Program (3 minute)

Method correlation between Bio-Rad VARIANT II TURBO Hemoglobin A1c Program with CDM 4.0 and VARIANT II TURBO Hemoglobin A1c Program with CDM 3.6T was evaluated using 40 EDTA whole blood samples ranging from (4.4% -11.6%) HbA1c. The results are presented in the following table:

VARIANT II TURBO Hemoglobin A1c Program Correlation

Regression Method	n	r^2	Slope	Intercept
Least Squares	40	0.9991	1.0174	0.0559

Precision:

VARIANT II TURBO Hemoglobin A1c Program

The following precision table provides comparison data on the precision between VARIANT II TURBO Hemoglobin A1c Program with CDM 4.0 vs. CDM 3.6T each utilizing EDTA whole blood patient samples.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol, EP5-A for the VARIANT II TURBO Hemoglobin A1c Program with CDM 4.0 and 3.6T. The protocols for both VARIANT II TURBO Hemoglobin A1c Program with CDM 4.0 and 3.6T are similar. In each duplicate daily run for both verification studies, duplicate aliquots of normal HbA1c and diabetic HbA1c patient samples and controls were each analyzed per run. The position of the precision specimens in each run was randomized to simulate normal laboratory conditions. The precision data for the VARIANT II TURBO with CDM 3.6T was over 20 working days while the data for VARIANT II TURBO with CDM 4.0 was over 10 working days.

Although precision samples are different, since they were run at different time periods, the precision results between the VARIANT II TURBO Hemoglobin A1c Program with CDM 4.0 and CDM 3.6T are equivalent. A summary of combined comparative precision results are presented in the following precision table.

VARIANT II TURBO HbA1c with CDM 4.0 vs. VARIANT II TURBO HbA1c with CDM 3.6T - Precision

	VII TURBO HbA1c with CDM 4.0		VII TURBO HbA1c with CDM 3.6T	
	Normal Sample	Diabetic Sample	Normal Sample	Diabetic Sample
n= (number of samples)	40	40	80	80
Mean (%HbA_{1c})	5.4	9.7	6.2	12.5
Within run (%CV)	0.9	0.9	0.8	0.5
Total Precision (%CV)	1.2	1.9	1.9	2.6

Conclusion:

The similarities of the intended use and the general performance characteristics and results of the newly described and evaluated **VARIANT II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System with CDM 4.0** are nearly identical to or logical extensions of those for cleared predicate program systems [i.e., VARIANT II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System with CDM 3.6T (k)040872]. Thus, one may conclude, based on the use of the same HPLC technology, and the nearly equivalent results obtained for the correlation and precision versus the corresponding results obtained with the predicate system that the new **VARIANT II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System with CDM 4.0** is substantially equivalent to the cleared and currently marketed predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jackie Buckley
Bio-Rad Laboratories, Inc.
Clinical System Division
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Hercules, California 94547

DEC - 1 2006

Re: k063400
Trade/Device Name: Varient II Turbo Hemoglobin A1c Program, Hemoglobin Testing System With CDM 4.0
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, LDM
Dated: November 8, 2006
Received: November 9, 2006

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 (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k063400

Device Name: Variant II Turbo Hemoglobin A1c Program, Hemoglobin Testing System With CDM 4.0

Indications For Use:

The Bio-Rad VARIANT II TURBO Hemoglobin A1C Program with CDM 4.0 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 TURBO Hemoglobin A1C Program with CDM 4.0 is intended for Professional Use Only. For In Vitro Diagnostic Use.

Measurement of percent hemoglobin A1C is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K063400