JUL 27 2009

Summary of Safety and Effectiveness

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: k090699.

Submitter:	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Drive, Hercules, California 94547 Phone: (510) 741-5309 FAX: (510) 741-3954
Contact Person:	Jackie Buckley Regulatory Affairs Representative III
Date of Summary Preparation:	March 12, 2009
Device Name:	VARIANT™ II TURBO HbA1c Kit – 2.0 (Catalog number 270-2455)
Classification Name:	Assay, Glycosylated Hemoglobin, LCP
Predicate Device:	VARIANT™ II Hemoglobin A1c Program (k)070452 Bio-Rad Laboratories (Catalog number 270-2101NU)
Intended Use:	The Bio-Rad VARIANT II TURBO HbA1c Kit – 2.0 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 HbA1c Kit – 2.0 is intended for Professional Use Only.
Indications for Use:	Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Description of the Device:

The VARIANT II TURBO Hemoglobin Testing System uses the principles of high performance liquid chromatography (HPLC). The VARIANT II TURBO HbA1c kit – 2.0 is based on chromatographic separation of Hemoglobin A1c on a cation exchange cartridge.

Technical Characteristics Compared to the Predicate:

The new VARIANT II TURBO HbA1c Kit – 2.0 (270-2455) and the predicate VARIANT II Hemoglobin A1c Program (270-2101NU) have the same technical characteristics that are summarized in the table below:

Characteristics	VARIANT II TURBO HbA1c – 2.0 (270-2455)	VARIANT II Hemoglobin A1c (270-2101NU) (k)070452
Analyte Measured: Reported	%Hemoglobin A1c	%Hemoglobin A1c
Intended Use	The Bio-Rad VARIANT II TURBO HbA_{1c} Kit – 2.0 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 HbA1c Kit – 2.0 is intended for Professional Use Only.	The Bio-Rad VARIANT II Hemoglobin A_{1c} 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 Hemoglobin A1c Program is intended for Professional Use Only.
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
Total Area Range	1.0 – 3.5 million µvolt•second	1.5 – 4.5 million µvolt•second
Calibration Frequency	After installation of the analytical cartridge	After installation of the analytical cartridge and once every 30 days
Kit size	2500 tests	1000 test
Cartridges Included in Kit	1 Cartridge (2500 tests)	1 Cartridge (1000 tests)
Buffer A and Buffer B formulation	Sodium Perchlorate Buffer	Tris-Bis Buffer
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:

Accuracy:

Method correlation between the VARIANT II TURBO HbA1c Kit – 2.0 (270-2455) and VARIANT II Hemoglobin A_{1c} Program (270-2101NU) was compared using 40 EDTA whole blood patient samples and 12 samples prepared by mixing EDTA whole blood patient samples with Lyphochek® Hemoglobin A1c Linearity Set samples in various ratios. The range of values on the VARIANT II TURBO HbA1c Kit -2.0 was from 2.6% to 19.0% HbA_{1c}. The results are presented in the following regression table.

Regression Method	n	R^2	Slope	Intercept
Least Squares	52	0.994	0.9621	0.4443

Precision:

The following table provides comparison data on the precision between the VARIANT II TURBO HbA1c Kit – 2.0 (270-2455) and VARIANT II Hemoglobin A1c (270-2101NU) Programs, each utilizing low and high EDTA whole blood patient samples, and both tested against samples with moderate (5.5/5.6) and high (8.8/11.4) % A1c content.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol, Vol.24, No. 25, EP5-A2 for the VARIANT II TURBO HbA1c Kit – 2.0 and the VARIANT II Hemoglobin A1c (270-2101NU). The protocols for both the VARIANT II TURBO HbA1c Kit – 2.0 and the VARIANT II Hemoglobin A1c Programs are similar.

For the VARIANT II TURBO HbA1c Kit – 2.0 and the VARIANT II Hemoglobin A1c Program protocol, six VARIANT II TURBO and six VARIANT II Hemoglobin Testing Systems at three Bio-Rad sites were utilized. Each site was provided with the same sample set and performed two replicates of each sample on each of 2 runs per day for 10 days.

Although the precision samples are different, since they were run at different time periods, the precision results between the VARIANT II TURBO Hemoglobin A1c (270-2255) and the current VARIANT II Hemoglobin A1c Program (270-2101NU) are equivalent. A summary of combined comparative precision results is presented in the following precision table.

VARIANT II TURBO HbA1c Kit – 2.0 (270-2455) and VARIANT II Hemoglobin A1c (270-2101NU) Precision

	VARIANT II TURBO HbA1c Kit – 2.0 (270-2455)		VARIANT II Hemoglobin A1c (270-2101NU)	
	Low Patient (HbA_{1c})	High Patient (HbA_{1c})	Low Patient (HbA_{1c})	High Patient (HbA_{1c})
n= (number of samples)	240	240	240	160
Mean	5.6	11.4	5.5	8.8
Within run (%CV)	0.78	0.39	0.9	0.6
Within Device Precision (%CV)	1.15	0.91	1.60	1.38

Linearity:

	VARIANT II TURBO HbA1c Kit – 2.0 (210-2455)	VARIANT II Hemoglobin A1c Program (210-2101NU)
Linear Range	3.5 – 19.0 % HbA1c	3.1 – 18.5 % HbA1c

Interfering Substances:

Interfering Substance	VARIANT II TURBO HbA1c Kit – 2.0 (270-2455)	VARIANT II Hemoglobin A1c (270-2101NU)
Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Lipids (Triglycerides)	No interference up to 6000 mg/dL	No interference up to 6000 mg/dL
EDTA	No interference up to 11X EDTA	No interference up to 11X EDTA
Hemoglobin F	25%	15%
Interference from HbS, HbC, HbE, HbD trait samples on %A1c	Two out of 7 hemoglobin AD-trait, 2 out of 11 hemoglobin AS-trait, 1 out of 12 hemoglobin AE-trait, and 3 out of 9 hemoglobin AC-trait patient samples at the clinically significant levels of 6% and 9% HbA1c exhibited differences of more than ±10% from values obtained using boronate affinity reference method.	No interference

Conclusion:

When considering the similarities of the intended use, the general characteristics of the two assays, the use of the same technology and the similar correlation, accuracy and linearity between the two methods, it can be concluded that the VARIANT II TURBO HbA1c Kit – 2.0 (270-2455) is substantially equivalent to the cleared and currently marketed predicate, VARIANT II Hemoglobin A_{1c} Program (270-2101NU).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Bio-Rad Laboratories, Inc.
c/o Jackie H. Buckley
4000 Alfred Nobel Dr.
Hercules, CA 94547

JUL 27 2009

Re: k090699
Trade/Device Name: VARIANT II TURBO HbA_{1c} Kit-2.0
Regulation Number: 21 CFR § 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: June 17, 2009
Received: June 18, 2009

Dear Jackie 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting 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): k090699

Device Name: VARIANT II TURBO™ HbA_{1c} Kit – 2.0

Indications For Use:

The Bio-Rad VARIANT™ II TURBO HbA_{1c} Kit -2.0 is intended for the percent determination of hemoglobin A_{1c} in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). Bio-Rad VARIANT™ II TURBO HbA_{1c} kit is intended for Professional Use Only.

Measurement of percent hemoglobin A_{1c} 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 Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090699