K140801

JUN 25 2014

Special 510(k) Summary – Device Modification

Introduction

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

Submitter

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Contact Person

Ebony McKinnies
Regulatory Affairs Representative III
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Date Submitted

April 23, 2014

Device Name

VARIANT™ II TURBO Link Hemoglobin A1c Program

Classification

Glycosylated hemoglobin assay, 21 CFR 864.7470 [LCP]

Predicate Device

Table 1: Predicate Device

Device Name	510(k) Number	Product Regulation and Code
VARIANT™ II TURBO Link Hemoglobin A1c Program	K070819	21 CFR 864.7470 [LCP]

Intended and Indications for Use

The Bio-Rad VARIANT II TURBO Link 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 Link Hemoglobin A1c Program is for use with the VARIANT II TURBO Link Hemoglobin Testing System interfaced with an automated sample transport system.

The Bio-Rad VARIANT II TURBO Link Hemoglobin A1c Program is Professional Use Only.

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

Description of Instrument

The VARIANT II TURBO Link Hemoglobin Testing System is the next generation VARIANT II TURBO Hemoglobin Testing System. It integrates the VARIANT II TURBO with the Sysmex HST-N (Hematology Sample Transportation)/XN-9000 TLA systems to allow management of patient sample tubes with A1c order on the same platform. The VARIANT II TURBO Link system communicates with the Sysmex HST-N/XN-9000 TLA hardware and software in order to receive, identify, inject, and analyze samples with an A1c order.

The VARIANT II TURBO Link Hemoglobin Testing System is a fully automated, high-throughput hemoglobin analyzer. It consists of three modules – the VARIANT II TURBO Link Chromatographic Station (VCS), the VARIANT II TURBO Link Sampling Station (VSS), and the Reagent Reservoir Module. In addition, a personal computer (PC) is used to control the VARIANT II TURBO Link system using Clinical Data Management (CDM™) software.

Table 2: FDA-cleared assays for use on the VARIANT II TURBO Link Hemoglobin Testing System with CDM Software

VARIANT II TURBO Link Assay	Assay Part No.	Component Names and Part Nos.	Explanation of Test
VARIANT II TURBO Link Hemoglobin A1c Program	270-2716	The assay contains the following components – ▪ Whole Blood Primer, 270-0352, 270-0351, 270-0352 ▪ Elution Buffer A, 270-2717 ▪ Elution Buffer B, 270-2718 ▪ Wash/Diluent Solution, 270-2729 ▪ CD-ROM, 270-2719 ▪ Cartridge Set, 270-22724 ▪ Sample Vials, 270-2149 ▪ Calibrator/Diluent Set Additional Required/Available components: ▪ Wash/Diluent Solution Set, 270-2730 ▪ Elution Buffer A Set ▪ Prefilters, 270-2713 ▪ Stainless Steel Prefilter Adapters, 270-2465 ▪ Microvial Adapters, 270-2720, 270-2721	The VARIANT II TURBO Link Hemoglobin A1c Program is a well established method of measuring the level of Hemoglobin A1c in red blood cells. Therapy for diabetes requires the long-term maintenance of a blood glucose level as close as possible to normal levels to minimize the risk of long-term vascular consequences.

Comparison to Predicate Device

The following table shows the similarities and differences between the predicate and modified device.

Table 3: VARIANT II TURBO Link Hemoglobin A1c Program

Feature	Predicate: Bio-Rad VARIANT™ II TURBO Link Hemoglobin A1c Program K070819	Modified device Bio-Rad VARIANT™ II TURBO Link Hemoglobin A1c Program K140801
Similarities		
Technology	Ion-exchange high performance liquid chromatography	
Sample type	Anticoagulated whole blood (EDTA)	

Feature	Predicate: Bio-Rad VARIANT™ II TURBO Link Hemoglobin A1c Program K070819		Modified device Bio-Rad VARIANT™ II TURBO Link Hemoglobin A1c Program K140801		
Calibrator	Human anticoagulated whole blood treated with EDTA				
Certification	Certified by the NGSP as traceable to the Diabetes Control and Complications Trial (DCCT) Reference method.				
Instrument Control	Windows Operating System with Proprietary Assay Software				
Kit configuration	1600 Tests: Whole Blood Primer (6 vials), Elution Buffer A (1 each), Elution Buffer B (1 each), Calibrator/Diluent Set (1 each), CD-ROM (1 each), Cartridge Set (1 each), Sample vials – package of 100 (2 each), Wash/Diluent Solution (1 each).				
Chemistry	Cation Exchange Matrix				
Safety Standards for Electrical Equipment for IVD Use	BS EN 61010 Certified				
Electromagnetic Compatibility	BS EN 61326 Certified				
Intended Use	The Bio-Rad VARIANT II TURBO Link 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 Link Hemoglobin A1c Program is for use with the VARIANT II TURBO Link Hemoglobin Testing System interfaced with an automated sample transport system. The Bio-Rad VARIANT II TURBO Link Hemoglobin A1c Program is for Professional Use Only.				
Performance Claims	No change, claims transferred from predicate device.				
Differences					
CDM Software	CDM Software version 4.1		CDM Software version 5.2.1		
Reporting Units	%HbA1c (NGSP)		% HbA_{1c} (NGSP), mmol/mol HbA_{1c} (IFCC), or %HbA_{1c} (JDS)		
Printing Options	Export text file to external printer		External printer and Export to PDF options		
VARIANT II TURBO Link Testing System Firmware	EPROM VCS 41.507 VSS 51.505 VSS PUMP 4.50	FLASH N/A	EPROM VCS 41.507 VSS 51.815 VSS PUMP 4.50	HST FLASH VCS 42.507 VSS 52.815 VSS Pump 5.0	XN 9000 FLASH VTCS 42.507 VTSS 52.815 VTSS PUMP 5.00
Automated Sampling Station	Sysmex HST Trackline		Sysmex HST or Sysmex XN-9000 Trackline		
Historical Database Review	N/A		Archive Viewer – this tool does not allow transmission to an LIS, and is not intended for repeat reporting.		

Description of Change

The software updates include customer requested features, whereas both software and firmware include specific defect fixes. When compared to the predicate device, there are no changes to the performance specifications, intended or indications for use, or operating principles. Moreover, Risk Analysis and Verification/Validation testing results demonstrate that the changes do not affect product safety, effectiveness, and substantial equivalency claims.

Risk Management Process for Device Modifications

In accordance with ISO 14971:2012, and internal risk management processes and procedures a defined risk analysis was used to identify, mitigate, or eliminate potential risks associated with the device modifications. For each identified risk, a Failure Mode and Effects Analysis (FMEA) was conducted. This was performed in a systematic manner by a trained risk assessment team until consensus was reached that an adequate analysis had been performed. The risk evaluation for the device software and firmware modifications included the following tasks:

- Reviewed modifications and design inputs to identify potential risks and hazards;
- Reviewed existing product risk tables and customer complaints to identify potential risks and hazards;
- Considered requirements of IEC 62304:2009, Software Design and Development processes and plan to identify potential risks and hazards;
- Identified and implemented risk mitigations and hazard controls through software, hardware, and labeling for misuse and use scenarios;
- Updated existing FMEA and Hazard Analysis tables with newly identified risks, software defects, residual risks, mitigations and hazard controls;
- Evaluated modified product using established verification and validation processes, plans and protocols with appropriate acceptance criteria that determined whether risk mitigations, hazard controls, and residual risks were as safe and effective as the predicate device;
- Conducted a comprehensive risk management review and wrote a Risk Management Report that summarized all risk activities and deemed the modified product safe, effective, and comparable to the predicate device.

Design verification/validation tests met established acceptance criteria.

Conclusion

When considering the similarities of the intended use, general features and characteristics of the assay, and use of the same technology, it can be concluded that the VARIANT II TURBO Link Hemoglobin A1c Program is substantially equivalent to the cleared and currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIO-RAD LABORATORIES, INC.
EBONY MCKINNIES
REGULATORY AFFAIRS REPRESENTATIVE III
4000 ALFRED NOBEL DR.
HERCULES CA 94547

June 25, 2014

Re: K140801
Trade/Device Name: VARIANT™ II TURBO Link Hemoglobin A1c Program
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP
Dated: May 23, 2014
Received: May 27, 2014

Dear Ms. McKinnies:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140801

Device Name
VARIANT™ II TURBO Link Hemoglobin A1c Program

Indications for Use *(Describe)*

The Bio-Rad VARIANT II TURBO Link 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 Link Hemoglobin A1c Program is for use with the VARIANT II TURBO Link Hemoglobin Testing System interfaced with an automated sample transport system.

The Bio-Rad VARIANT II TURBO Link Hemoglobin A1c Program is Professional Use Only.
Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S