K112015

NOV 22 2011

510(k) Summary – Premier Hb9210™

510(k) Number Assigned:	
Introduction:	Trinity Biotech hereby submits this summary for the Premier Hb9210™ traditional 510(k) in accordance with the requirements of 21 CFR 807.92 for the demonstration of safety and effectiveness and substantial equivalence to the patented K891235 boronate affinity HPLC analyzer and HbA1c assay.
Submitter and Owner:	Trinity Biotech 4231 E. 75th Terrace Kansas City, MO 64132 USA Contact Person: Britt Einspahr, Manager of Quality Assurance & Compliance Email: Britt.Einspahr@TrinityUSA.Com Phone: 716-483-7402 Fax: 816-214-4410 Contact Person: Bonnie DeJoy, Corporate VP of RA (Official Correspondent) Email: Bonnie.DeJoy@TrinityUSA.Com Phone: 716-483-3851 Extension 1030 Fax: 716-488-1990
Date Prepared:	8 July 2011
Device Name:	Proprietary Name: Premier Hb9210™ HbA1c Analyzer Common Names: Premier Hb9210™ Premier – HbA1c Premier – A1c Classification Name: Glycosylated Hemoglobin Assay
Classification:	Class II, IVD
Product Code:	LCP
Device Description:	The Premier Hb9210™ is an update of the predicate HPLC device, the Ultra2, which is the current model under K891235. The Premier Hb9210™ is a compact, integrated HPLC system and workstation with the Trinity Biotech AFFINITY Software for the quantitative determination of glycated hemoglobin using the patented boronate affinity chemistry with high performance liquid chromatography.

Intended Use: The Premier Hb9210™ system is intended for the quantitative measurement of hemoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycemic control in individuals with diabetes mellitus. For *in vitro* diagnostic use only."

Predicate Device: K891235 – Boronate Affinity HPLC Method – Current Model: *ultra*^{2}

Comparison to Predicate: The following table provides comparison of the Premier Hb9210™ and HbA1c assay to the predicate device.

Aspect or Feature	Predicate (K891235)	Premier Hb9210™
Intended Use	For the quantitative measurement of the percentage of total glycated hemoglobins in whole blood. For *in vitro* diagnostic use.	The Premier Hb9210™ system is intended for the quantitative measurement of hemoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycemic control in individuals with diabetes mellitus. For *in vitro* diagnostic use only."
Chemistry	Patented Boronate Affinity	Same
Sample Types	Venous EDTA or Finger Stick	Venous EDTA, Heparin or Sodium Fluoride or Finger Stick
Method	HPLC	Same
HbA1c Species Separation	Chromatography	Same
Instrumentation Control	Windows Operating System with Proprietary Assay Software	Same
Automation	Completely Automated	Same
Operation	Continuous	Same
Column	Boronate Affinity Matrix	Same
Column Matrix	Replenished, Re-Used	Same
Reagents	Boronate Affinity Chemistry	Same
Solution Phases	2	Same
Optical Phases	1	Same
Chromatography Integration	Peak Separation and Area Determination	Same
Detector UV Wavelength	413 nm	Same
Detector UV Light	Incandescent Lamp	LED

Aspect or Feature	Predicate (K891235)	Premier Hb9210™
Calibration	With Each Run Cal Data Used For Each Sample	Same
Sample ID	Operator Input or Bar Code Reader	Same
Controls	With each run per clinical laboratory policies	Same
Standards / Traceability	IFCC, NGSP	Same
Test Time	1 Result per 2 Minutes	1 Result per 1 Minute
Results Output	Display and Print	Same
Printout	Automatic, User Select	Same
Reporting Units	% HbA1c (NGSP / DCCT)	% HbA1c (NGSP / DCCT) mmol/mol (IFCC)
Equation Used for Final HbA1c Value	%HbA1c = 0.588 * %GHb + 1.706	%HbA1c = 0.588 * %GHb + 1.706 mmol/mol = (%HbA1c – 2.15) / 0.0915
Safety Stds for Electrical Equip for Lab and IVD Use	IEC61010 Certified	Same
Electromagnetic Compatibility	EMC Certified	Same

Summary of Performance Testing

***Intra*-run Precision – All sites – Hemolysate:** The between-run precision study consists of three hemolysate samples (1:100 dilution), representing normal, decision point and abnormal levels of %HbA1c. They were analyzed on 20 non-consecutive days. One internal and 2 external sites were involved, each site was provided with the same sample set (aliquotted and frozen whole blood) and directed to perform 2 analyses of each sample per run with 2 runs per day (a total of 80 replicates of each level per site, 240 replicates overall. The study lasted 35 calendar days. The estimates of imprecision for each sample result obtained from all 3 study sites (all results averaged) analysis are given in the table below:

Actual number of days involved in the experiment, and number of sites:	49days, 3 sites
Actual total number of runs (if applicable):	120 total runs
Total number of observations (including controls):	1200 total observations
Number of instruments/devices used in the evaluation, and how results were pooled:	3 instruments, individual values not pooled
Number of reagent lots:	1 reagent lot number per reagent/column
Number of calibration cycles and calibration lots:	14 total recalibrations once study started, 1 lot of Calibrator used.

All Sites:

Concentrations at which claim is made; %HbA1c	5.76	7.07	10.96
Estimate of repeatability SD, (S_r)	0.07	0.05	0.09
Repeatability %CV = (S_r/mean)*100	1.26	0.72	0.85
Estimate of within-device precision SD, (S_T)	0.09	0.09	0.16
Within-device precision %CV = (S_T/mean)*100	1.62	1.28	1.50

***Intra*-run Precision – Individual Sites – Hemolysate:**
The between-run precision study data for each individual site is as follows:

Site A: External

Concentrations at which claim is made; %HbA1c	5.70	7.06	10.96
Estimate of repeatability SD, (S_r)	0.07	0.06	0.09
Repeatability %CV = (S_r/mean)*100	1.24	0.79	0.78
Estimate of within-device precision SD, (S_T)	0.10	0.11	0.18
Within-device precision %CV = (S_T/mean)*100	1.84	1.58	1.62

Site B: External

Concentrations at which claim is made; %HbA1c	5.71	7.08	10.88
Estimate of repeatability SD, (S_r)	0.05	0.06	0.09
Repeatability %CV = (S_r/mean)*100	0.85	0.79	0.85
Estimate of within-device precision SD, (S_T)	0.08	0.09	0.18
Within-device precision %CV = (S_T/mean)*100	1.47	1.20	1.62

Site C: Internal

Concentrations at which claim is made; %HbA1c	5.85	7.06	11.03
Estimate of repeatability SD, (S_r)	0.10	0.04	0.10
Repeatability %CV = (S_r/mean)*100	1.68	0.57	0.92
Estimate of within-device precision SD, (S_T)	0.09	0.07	0.14
Within-device precision %CV = (S_T/mean)*100	1.55	1.04	1.27

Accuracy – The r^2 value when analyzing IFCC HbA1c Standards is 0.9998 and the r^2 value when analyzing 51 samples vs. *ultra*[2] is 0.9976.

Linearity – The demonstrated linearity is from 3.7% - 18.5%HbA1c.

Substantial Equivalence: The Trinity Biotech Premier Hb9210™ and the predicate device are based on the same method, technology, materials, and engineering with the Premier Hb9210™ being a new model in the high performance liquid chromatography boronate affinity product line. All key elements and performance aspects are either identical or functionally equivalent. In conclusion, the Premier Hb9210™ is functionally equivalent and safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 2 2 2011

Primus Corporation DBA Trinity Biotech
c/o Britt Einspahr
Manager of Quality Assurance & Compliance
4231 E 75th Terrace
Kansas City, MO 64132

Re: K112015

Trade Name: Premier Hb9210
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: October 07, 2011
Received: October 17, 2011

Dear Britt Einspahr:

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

Enclosure

Indications for Use

510(k) Number (if known): K112015

Device Name: Premier Hb9210

Indications for Use:

The Premier Hb9210 System is intended for the quantitative measurement of hemoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycemic control in individuals with diabetes mellitus. For in vitro diagnostic use only.

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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