AUG 27 2010

Section 5

510(K) Summary

K100304

K100304

510k Summary

AUG 27 2010

Tosoh ST AIA-PACK HbA1c

Date: **August 20, 2010**

Submitter:
Tosoh Bioscience, Inc.
3600 Gantz Road
Grove City, OH 43123

Contact Person:
Judith K. Ogden
Director, New Business and Technical Development
Tosoh Bioscience, Inc.
6000 Shoreline Court, Suite 101,
South San Francisco, CA 94080
Phone: (650) 636-8112

Device Name: ST AIA-PACK HbA1c

Classification Name:
Class II
LCP
21 CFR 864.7470 Glycosylated Hemoglobin Assay

Predicate Device:
K011434
Tosoh Automated Glycohemoglobin Analyzer
HLC-723G7
Manufactured by Tosoh Corporation.

K100304

Tosoh Bioscience, Inc.

510(k) Summary

ST AIA-PACK HbA1c

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Description:

The ST AIA-PACK HbA1c is an enzyme immunoassay which, after pretreatment, is performed entirely in ST AIA-PACK HbA1c test cups. The whole blood sample must first be pretreated prior to immunocomplex formation between HbA1c and sheep anti-HbA1c polyclonal antibody. Sample pretreatment is performed to achieve complete hemolysis of erythrocytes and to expose carbohydrate part of HbA1c in the whole blood sample using ST AIA-PACK HbA1c PRETREATMENT SOLUTION (40 °C, 20 minutes). HbA1c present in the pretreated test sample is captured on the magnetic beads along with hemoglobin and bound with enzyme-labeled sheep anti-HbA1c polyclonal antibody in the AIA-PACK test cup. The beads are washed to remove the unbound materials and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled polyclonal antibody that binds to the beads is directly proportional to the HbA1c concentration in the test sample. A standard curve using a range of known standard percent concentrations aligned to NGSP % is constructed and unknown HbA1c percent concentrations are calculated using this curve.

The following products are required to use the Tosoh AIA-PACK HbA1c.

ST AIA-PACK HbA1c CALIBRATOR SET
ST AIA-PACK HbA1c PRETREATMENT SOLUTION
AIA-PACK HbA1c CONTROL SET

Device Intended Use:

ST AIA-PACK HbA1c is designed for In Vitro Diagnostic Use Only for the quantitative measurement for percent concentration of Hemoglobin A1c (HbA1c) in EDTA whole blood on Tosoh AIA System Analyzer. HbA1c measurement is used in the management and treatment of diabetes.

Substantial Equivalence:

Similarities between ST AIA-PACK HbA1c and Tosoh Automated Glycohemoglobin Analyzer HLC-723G7

Specifications	ST AIA-PACK HbA1c	Tosoh Automated Glycohemoglobin Analyzer HLC-723G7 K011434
Intended Use	ST AIA-PACK HbA1c is designed for In Vitro Diagnostic Use Only for the quantitative measurement for percent concentration of Hemoglobin A1c (HbA1c) in EDTA whole blood on Tosoh AIA System Analyzer. HbA1c measurement is used in the management and treatment of diabetes.	
Sample Type	EDTA whole blood	EDTA whole blood
Assay Range	3.0 to 14%	3.0 to 18.4%
Reference Range	3.8 to 6.0% for persons without diabetes	4.2 to 5.8%
Calibrator Set	ST AIA-PACK HbA1c Calibrator Set 6 point aligned to IFCC and NGSP	Hemoglobin A1c Calibrator Set 2 point aligned to IFCC and NGSP K011434
Cross reactivity to Hb variants HbC, HbD	NO	NO

Differences between ST AIA-PACK HbA1c and Tosoh Automated Glycohemoglobin Analyzer HLC-723G7

Specifications	ST AIA-PACK HbA1c	Tosoh Automated Glycohemoglobin Analyzer HLC-723G7 K011434
Methodology	Immuno Enzymometric Assay (IEMA) using fluorescence detection	HPLC Method
Assay time	38 minutes (10 min. incubation and 20 min. pretreatment)	2.2 minutes.
Cross reactivity with HbF	>10% of HbF	15%
Cross reactivity with HbS	1 out 5 variant HbS specimens was outside the criteria of +/- 10% recovery.	NO

Comparative Analysis (Correlation)

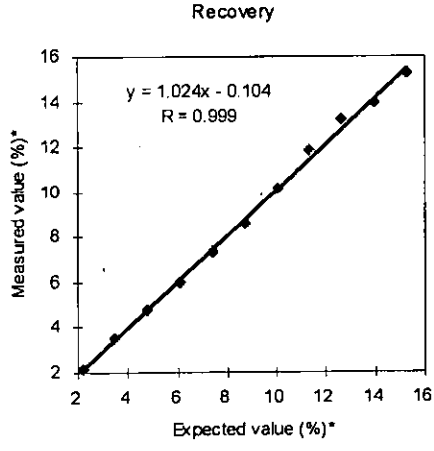
The correlation for ST AIA-PACK HbA1c was determined based on guidance from CLSI Protocol EP9-A2.

The correlation study between Tosoh Automated Glycohemoglobin Analyzer HLC-723G7 (HPLC method) NGSP % (x) and ST AIA-PACK HbA1c NGSP % (y) was carried out using 126 patient specimens.

Regression Analysis		
	Deming	Regular
Slope:	1.027 (1.006 to 1.047)	1.020 (1.000 to 1.040)
Intercept:	-0.168 (-0.326 to -0.011)	-0.120 (-0.277 to -0.037)
95% Confidence Intervals are shown in parentheses		
Corr Coef (R):	0.99	
Bias:	0.025	
Points (Plotted/Total):	126/126	
Result Ranges:	3.0 to 13.9% (AIA-1800); 2.8 to 14.6% (G7)	

Recovery

A recovery study was performed for ST AIA-PACK HbA1c to support the measuring range of 3-14%* based on guidance from CLSI Protocol EP6-A. The maximum recovery was 2.2% and the minimum recovery was –4.9%.



*: HbA1c (NGSP %)

Note: High sample and low sample have the same hemoglobin concentration (approximately 14 g/dL).

Precision

The precision for ST AIA-PACK HBA1c was determined based on guidance from CLSI Protocol EP5-A2.

Precision was assessed by assaying three levels of unaltered EDTA whole blood specimens. Estimates of total and within-run precision were obtained from measurements of 2 replicates in a single run, 2 times a day for 20 non-consecutive days. This equaled to a total of 40 runs and 80 determinants.

Within Run Precision

Within-run precision was determined to be from 1.1 to 1.9%

Specimen	Reagent Set # 1			Reagent Set # 2			Reagent Set # 3		
	Mean (%)*	Pooled SD (%)*	CV (%)	Mean (%)*	Pooled SD (%)*	CV (%)	Mean (%)*	Pooled SD (%)*	CV (%)
HWB-1**	5.3	0.096	1.8	5.5	0.099	1.8	5.5	0.090	1.6
HWB-2**	8.1	0.093	1.1	8.2	0.137	1.7	8.2	0.122	1.5
HWB-3**	13.1	0.244	1.9	13.0	0.192	1.5	13.0	0.204	1.6

*(%): HbA1c (NGSP%), ** HWB: Unaltered Human EDTA Whole Blood Specimen.

Total precision

Total precision was determined to be from 1.9 to 4.0%

Specimen	Reagent Set # 1			Reagent Set # 2			Reagent Set # 3		
	Mean (%)*	Pooled SD (%)*	CV (%)	Mean (%)*	Pooled SD (%)*	CV (%)	Mean (%)*	Pooled SD (%)*	CV (%)
HWB-1**	5.3	0.175	3.3	5.5	0.120	2.2	5.5	0.109	2.0
HWB-2**	8.1	0.256	3.2	8.2	0.161	1.9	8.2	0.158	1.9
HWB-3**	13.1	0.528	4.0	13.0	0.314	2.4	13.0	0.310	2.4

*(%): HbA1c (NGSP%), ** HWB: Unaltered Human EDTA Whole Blood Specimen.

Limit of Detection (LoD) and Limit of Quantitation (LoQ):

This section is not applicable.

Standards:

Number	FDA Recognition Number	Revision	Title
C28-A3 NCCLS	7-202	09/08/09	How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition
EP5-A2 NCCLS	7-110	8/20/04	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition
EP6-A NCCLS	7-193	4/1/03	Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline
EP9-A2 NCCLS	7-92	9/20/02	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition

Conclusion:

The Tosoh Bioscience, Inc. ST AIA-PACK HbA1c ASSAY is substantially equivalent to the Tosoh Automated Glycohemoglobin Analyzer HLC-723G7 (K011434), for the quantitative measurement of HbA1c in EDTA whole blood samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Tosch Bioscience, Inc.
c/o Ms. Judy Ogden
6000 Shoreline Court, Suite 101
South San Francisco, CA 94080

AUG 2 7 2010

Re: k100304
Trade/Device Name: Tosoh ST AIA-PACK HbA1c
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIT, JJY
Dated: August 5, 2010
Received: August 6, 2010

Dear Ms. Ogden:

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 class II (Special Controls), 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). 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 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.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K100304

Indication for Use

510(k) Number (if known): K100304

Device Name: Tosoh ST AIA-PACK HbA1c

Indication For Use: ST AIA-PACK HbA1c is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement for percent concentration of Hemoglobin A1c (HbA1c) in EDTA whole blood on Tosoh AIA System Analyzer. HbA1c measurement is used in the management and treatment of diabetes.

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Doug Rhenhen

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K100304

Indication for Use

510(k) Number (if known):	k100304
Device Name:	Tosoh ST AIA-PACK HbA1c Calibrator Set
Indication For Use:	The ST AIA-PACK HbA1c CALIBRATOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of ST AIA-PACK HbA1c Assay.

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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Evaluation and Safety

k100304

Indication for Use

510(k) Number (if known):	k100304
Device Name:	Tosoh ST AIA-PACK HbA1c Control Set
Indication For Use:	The AIA-PACK HbA1c CONTROL SET is intended for IN VITRO DIAGNOSTIC USE ONLY for performing quality control procedures with the ST AIA-PACK HbA1c Assay.

Prescription Use __√__ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Evaluation and Safety

K100304

Indication for Use

510(k) Number (if known):	k100304
Device Name:	Tosoh ST AIA-PACK HbA1c Pretreatment Solution
Indication For Use:	The ST AIA-PACK HbA1c PRETREATMENT SOLUTION is intended for IN VITRO DIAGNOSTIC USE ONLY for the pretreatment of the patient samples or AIA-PACK HbA1c CONTROL SET for the ST AIA-PACK HbA1c assay.

Prescription Use ___√___ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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