

K07132

SEP 16 2008

510(k) SUMMARY

**Tosoh Bioscience, Inc.'s
Automated Glycohemoglobin Analyzer HLC-723G8 and
Hemoglobin A1c Calibrator Set**

Submitter's Name, Address, Telephone Number, and Date Prepared

Tosoh Bioscience, Inc.
6000 Shoreline Ct., Ste. 101
South San Francisco, CA 94080

Phone: (800) 248-6764
Facsimile: (650) 615-0415
Date Prepared: April 24, 2008

Contact Person:

Charles Gill
Manager, Regulatory Affairs/Quality Assurance
Tosoh Bioscience, Inc.
3600 Gantz Road
Grove City, OH 43123
Phone: (614) 317-1909

Name of Device and Name/Address of Sponsor

Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set
Tosoh Bioscience, Inc.
6000 Shoreline Ct., Ste. 101
South San Francisco, CA 94080
Phone: (800) 248-6764
Fax: (650) 615-0415

Common or Usual Name

Glycosylated Hemoglobin Assay

Classification Name

Assay, Glycosylated Hemoglobin
Calibrator, Primary

Regulation and Product Code

21 C.F.R. § 864.7470, LCP
21 C.F.R. § 862.1150, JIS

Predicate Device

Tosoh Bioscience, Inc.'s G7 Automated HPLC Analyzer (K011434)

Intended Use / Indications for Use

The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 is intended for IN VITRO DIAGNOSTIC USE for the measurement of hemoglobin A1c (HbA1c) in whole blood specimens. Hemoglobin A1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

The Hemoglobin A1c Calibrator Set is a reference agent designed for calibrating the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8.

Technological Characteristics

The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (G8) is an automated High Performance Liquid Chromatography (HPLC) system that separates and reports stable A1c (sA1c) percentage in whole blood. The operational portion of the G8 is composed of a sampling unit, liquid pump, degasser, column, detector, microprocessors, sample loader, floppy disk drive unit, operation panel, and a printer.

The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 uses non-porous ion-exchange high performance liquid chromatography (HPLC) for rapid, accurate and precise separation of the stable form of HbA1c from other hemoglobin fractions. The G8 uses a cation exchange column and separates the usual hemoglobin components in the blood into six fractions, A1a, A1b, F, L-A1c, sA1c, and A0. The separation is done by eluting the hemoglobins from the column with a stepwise elution of three elution buffers containing different salt concentrations. The result report is printed out and can be stored on a digital media. The result report includes a sample ID, date, percentage and retention time of each fraction, sA1c percentage and total A1 percentage (A1a + A1b + sA1c), along with a chromatogram of the elution pattern of the hemoglobin fractions. If a sample contains a hemoglobin variant, the column elutes the material depending upon its charge.

The calibrator set consists of two levels of calibrator, the low level in the non-diabetic range and the high level in the diabetic range. These two calibrators are used to establish a reference curve from which to establish the percentage of HbA1c in patient and control samples.

Performance Data

Tosoh Bioscience, Inc., has conducted substantial performance testing on the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set, including interference testing, variant interference testing, method comparison testing with the predicate, dilution (total area/linearity), recovery/linearity testing, intra- and inter-assay precision testing, total precision/reproducibility testing, traceability, and analytic

specificity testing. In addition, Tosoh Bioscience, Inc., compared the performance of the the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set to its predicate device. A total of 114 specimens over a range of 4.0 to 16.8 % were compared. The difference between the two devices was within the allowable error range for all 114 of 114 specimens ($100\% \pm 0.5$). In all instances, the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set functioned as intended and measurement of A1c and Total HbA was as expected.

Substantial Equivalence

The Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set is as safe and effective as the predicate device. The Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set is as safe and effective as the predicate device. Thus, the Automated Glycohemoglobin Analyzer HLC-723G8 and Hemoglobin A1c Calibrator Set is substantially equivalent.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 16 2008

Tosoh Bioscience, Inc.
c/o Mr. Charles P. Gill
Manage, Regulatory Affairs/Quality Assurance
6000 Shoreline Court, Ste. 101
South San Francisco, CA 94080

Re: k071132

Trade/Device Name: Automated Glycohemoglobin Analyzer HLC-723G8
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP, JIS
Dated: August 25, 2008
Received: August 25, 2008

Dear Mr. Gill:

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).

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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) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

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): K071132

Device Name: **G8 Automated Glycohemoglobin Analyzer HLC-723G8**

Indication For Use: **The G8 Automated Glycohemoglobin Analyzer HLC-723G8** is intended for IN VITRO DIAGNOSTIC USE for the measurement of hemoglobin A1c (HbA1c) in whole blood specimens. A1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

Ann Chappie
Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K071132

Indications for Use

510(k) Number (if known): K071132

Device Name: **Hemoglobin A1C Calibrator Set**

Indication For Use: **The A1C Calibrator Set** is a reference agent designed for calibrating Tosoh Automated Glycohemoglobin Analyzer HLC-723G8.

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 Device Evaluation and Safety (OIVD)



Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K071132