K011434

SEP 1 8 2001

510(k) Summary

Tosoh G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode

Submitter:

Tosoh Medics, Inc.
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Contact Person:

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Date of Summary Preparation:

August 23, 2001

Device Name:

G7 Automated
HPLC Analyzer: HbA1c Variant Analysis Mode

Classification Name:

Class II, LCP
21 CFR 864.7470 Glycosylated Hemoglobin Assay

Predicate Device:

A1c 2.2 Plus Automated Glycohemoglobin Analyzer
Tosoh Medics, Inc.
South San Francisco, CA
K972265

Device Description:

The G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode 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 HPLC G7 is composed of a sampling unit, liquid pump, degasser, column, detector, microprocessors, sample loader, floppy disk drive unit, operation panel and a printer.

The G7 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 gradient of three elution buffers containing different salt concentrations. The result report is printed out from the on-board printer and can be stored on a floppy disk from the on-board floppy disk drive. The data can be transmitted to a host computer. 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 software compares the retention times to "known windows" and designates the material as P0X or H-VX if it does not match a defined window.

All automated processes in the G7 are controlled by internal microprocessors, using software downloaded via the on-board floppy disk drive.

Statement of Intended Use:

The G7 Automated HPLC Analyzer - HbA1c Variant Analysis Mode is a high pressure liquid chromatography system intended for IN VITRO DIAGNOSTIC USE ONLY. Glycosylated hemoglobin measurements obtained by this device are used in the management and treatment of diabetes.

Substantial Equivalence:

Comparison Data:

The G7 Automated HPLC Analyzer - HbA1c Variant Analysis Mode is substantially equivalent in intended use and technological features to instrument systems in commercial distribution, that are used to measure the glycohemoglobin level in the blood by HPLC methodology.

Specifically, the G7 Automated HPLC Analyzer – HbA1c Variant Analysis Mode is substantially equivalent to the Tosoh A1c 2.2 Plus Automated Glycohemoglobin Analyzer (see K972265) which has been reviewed and cleared to market by FDA. A comparison of the capabilities and specifications of these two systems is provided in Table 1. Pertinent similarities and differences between the analyzers are presented in detail below.

Table 1

G7 Automated HPLC vs. A1c 2.2 Plus Comparison

	G7 – Hb A1c Variant Analysis Mode	A1c 2.2 Plus
Intended Use	Quantitative measurement of Hb A1c and Total Hb A	Quantitative measurement of Hb A1c and Total Hb A
Methodology	HPLC	HPLC
Column	Non-porous cation exchange	Non-porous cation exchange
Reported result	Peak resolution: A1a, A1b, F, LA1c, SA1c, A0 and variant (as P0X or H-VX)) Percentage of SA1c and Total A1	Peak resolution: A1a, A1b, F, LA1c, SA1c, A0 and variant (as HbS+) Percentage of SA1c and Total A1
Detection method	Visible wavelength detector 415 nm (sample) 500 nm (reference)	Visible wavelength detector 415 nm (sample) 500 nm (reference)
Microprocessor	Yes	Yes
User Input	Pressure sensitive LCD	Pressure sensitive LCD
Visual display	LCD display	LCD display
Throughput	2.2 minutes per sample	3.0 minutes per sample
Automated	Yes	Yes
Calibration	2 point	2 point
Sample type	Whole blood (undiluted or diluted)	Whole blood (undiluted or diluted)
Sample volume	3 uL	5 uL
Auto Dilution	Yes	Yes
Sample loading capacity	90 or 290 (automatic)	50 or 90 or 290 (automatic)
Sample holder	Primary tube or Sample cup	Primary tube or Sample cup
Printer	Thermal	Thermal
Bar-Code Capability	Yes	Yes
RS-232C	Yes, Bi-directional	Yes, Uni-directional

Comparative Analysis

Comparative analysis studies were performed with patient samples obtained from 230 patients by assaying the samples with the G7 Automated HPLC Analyzer in the HbA1c Variant Mode and the A1c 2.2 Plus Automated Glycohemoglobin Analyzer. Least squares linear regression analysis yields the following statistics:

Comparative Analysis: G7 Automated HPLC vs. A1c 2.2 Plus

Slope:	1.001
Intercept:	-0.12
Correlation Coefficient:	0.9987
Range of Samples (%):	3.4 – 15.9
Number of Samples	230

Precision studies demonstrated intra-run precision %CVs of 0.9% or less and inter-run precision %CVs of 1.6% or less. Total precision at a HbA1c mean of 5.79% was 1.12% while at a mean value of HbA1c of 10.90%, the total precision was 0.71%. Recovery studies performed with samples mixed in specified ratios generated recoveries of 100% to 102%.

Conclusion:

Considering the excellent correlation between the Tosoh G7 Automated HPLC – HbA1c Variant Analysis Mode and the A1c 2.2 Plus, it can be concluded that the G7 Automated HPLC Analyzer – HbA1c Variant Analysis Mode is substantially equivalent to the A1c 2.2 Plus Automated Glycohemoglobin Analyzer, which has been 510(k) cleared. Based on the establishment of substantial equivalence, the safety and effectiveness of the Tosoh G7 HPLC is confirmed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

Ms. Lois Nakayama
TOSOH Medics, Inc.
347 Oyster Point Boulevard
Suite 201
South San Francisco, California 94080

Re: K011434
Trade Name: G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode
Regulation Number: 21 CFR § 864.7470
Regulatory Class: II
Product Code: LCP
Dated: July 13, 2001
Received: July 19, 2001

Dear Ms. Nakayama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TOSOH MEDICS, INC.

TOSOH

PREMARKET NOTIFICATION

INDICATION FOR USE STATEMENT

G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode

The G7 Automated HPLC Analyzer is a high pressure liquid chromatography system intended for IN VITRO DIAGNOSTIC USE ONLY. Glycosylated hemoglobin measurements obtained by this device are used in the management and treatment of diabetes.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011434

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