



Food and Drug Administration
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ASAHI KASEI PHARMA CORPORATION
C/O CHRIS SLOAN
QUINTILESIMS
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ROCKVILLE MD 20852

Re: K170147
Trade/Device Name: Lucica Glycated Albumin-L
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP
Dated: September 12, 2017
Received: September 12, 2017

Dear Chris Sloan:

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,


Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170147

Device Name

Lucica® Glycated Albumin-L

Indications for Use (Describe)

The Lucica® Glycated Albumin-L is intended to be used for the quantitative measurement of glycated albumin in human serum on compatible clinical chemistry analyzers. The measurement of glycated albumin is useful for the intermediate term (preceding 2-3 weeks) monitoring of glycemic control in patients with diabetes. For in vitro diagnostic use only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY FOR K170147

Lucica[®] Glycated Albumin-L

510(k) Owner

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Date Prepared: October 9, 2017

Subject Device Name:

Trade Names Lucica[®] Glycated Albumin-L

Common or usual name Glycated albumin assay

Regulatory Information

Regulation Description	Product Code	Device Class	Regulation Number	Classification Panel
Glycosylated Hemoglobin Assay	LCP	II	21 CFR 864.7470	Hematology (81)

Submission Type: Traditional 510(k)**Predicate Device**

The Lucica[®] Glycated Albumin-L is equivalent to the following FDA-cleared assay:

- Fructosamine Test Kit [Randox Laboratories, Ltd (K023763)]

Device DescriptionLucica[®] Glycated Albumin-L:

Lucica[®] Glycated Albumin-L contains two glycated albumin reagents and two albumin reagents. The kit employs liquid reagents that require no preparation.

Calibrator for Lucica[®] Glycated Albumin-L:

Calibrators are supplied by Asahi Kasei Pharma Corporation to calibrate the Lucica[®] Glycated Albumin-L. The calibrators are available in two concentrations, Low (L) and High (H). The user should refer to the instrument operations manual for analyzer-specific calibration procedures.

Control for Lucica[®] Glycated Albumin-L:

Controls are supplied by Asahi Kasei Pharma Corporation for use with the Lucica[®] Glycated Albumin-L. The controls are available in two concentrations, Low (L) and High (H).

Indications for Use

The Lucica[®] Glycated Albumin-L is intended to be used for the quantitative measurement of glycated albumin in human serum on compatible clinical chemistry analyzers. The

measurement of glycated albumin is useful for the intermediate term (preceding 2-3 weeks) monitoring of glycemic control in patients with diabetes. For in vitro diagnostic use only.

Comparison of Intended Use / Indications for Use and Technological Characteristics to Predicate Device

Table 1 Comparison of Assays

	Lucica[®] Glycated Albumin-L	Randox Fructosamine Test Kit (K023763) (Predicate)	Substantial Equivalence
REAGENT KIT Intended Use / Indications for Use	The Lucica [®] Glycated Albumin-L is intended to be used for the quantitative measurement of glycated albumin in human serum on compatible clinical chemistry analyzers. The measurement of glycated albumin is useful for the intermediate term (preceding 2-3 weeks) monitoring of glycemic control in patients with diabetes. For in vitro diagnostic use only.	The Randox Laboratories Limited Fructosamine test kit is an in vitro diagnostic enzymatic assay for the quantitative determination of glycated protein (fructosamine) in human serum or plasma. Measurement of glycated serum protein is representative of the mean blood glucose levels over the preceding 2-3 weeks. For in vitro diagnostic use only.	Yes
Sample Type	Serum	Serum or plasma	Yes
Methodology	Enzymatic assay	Enzymatic assay	Yes

Performance Testing

The following data represent the typical performance of Lucica[®] Glycated Albumin-L. The data were collected on the FDA-cleared Roche/Hitachi Modular P Chemistry system.

1. Analytical Performance:

a. Precision/Reproducibility

A precision study of the Lucica[®] Glycated Albumin-L was performed according to CLSI Guideline EP05-A3.

Single site: Repeatability and within-laboratory precision was established by testing five serum sample pools. Each sample was assayed twice per run, two runs per day, for 20 testing days (N=80). The repeatability and within-laboratory precision of glycated albumin values in Lucica[®] Glycated Albumin-L expressed in %CV were not more than 2.6% and 3.3%, respectively. The results are summarized in Table 2.

Table 2 Single Site Precision Summary Table of Glycated Albumin Values (mmol/mol)

Sample	Target Value (mmol/mol)	Mean (mmol/mol)	N	Repeatability		Within-Laboratory	
				%CV	SD	%CV	SD
Pool serum 1	183	185.2	80	1.7%	3.1	2.2%	4.0
Pool serum 2	224	228.0	80	0.8%	1.7	1.1%	2.6
Pool serum 3	355	359.9	80	0.7%	2.6	0.9%	3.2
Pool serum 4	863	877.7	80	0.8%	7.0	0.9%	7.8
Pool serum 5	226	229.6	80	2.6%	6.0	3.3%	7.6

Abbreviations: %CV, coefficient of variation expressed as a percentage; SD, standard deviation

Multisite: Multisite (3 sites) precision was established by testing three serum sample pools at three different laboratories. Each sample was assayed five replicates per run, one run per day, for five testing days (N=25). In the multisite precision study, the overall reproducibility of glycated albumin values were not more than 1.6% CV. The results are summarized in Table 3.

Table 3 Summary of the Multisite Precision Study (overall) of Glycated Albumin Values (mmol/mol)

Sample	N	Target Value (mmol/mol)	Mean (mmol/mol)	Repeatability		Within-Laboratory		Reproducibility	
				%CV	SD	%CV	SD	%CV	SD
Pool serum 1	75	183	187.7	0.8%	1.6	1.0%	1.9	1.6%	3.0
Pool serum 2	75	355	363.1	0.7%	2.7	0.9%	3.2	0.9%	3.2
Pool serum 3	75	863	888.2	0.7%	6.4	0.8%	7.4	0.9%	8.2

Abbreviations: %CV, coefficient of variation expressed as a percentage; SD, standard deviation

b. Linearity

The linearity study of the Lucica[®] Glycated Albumin-L was performed according to CLSI Guideline EP6-A. The linearity study of the glycated albumin (GA) value used a lowest and a highest GA value serum sample pools. These samples were mixed together in varying ratios. Samples were analyzed in triplicate in one run. The study supported that the GA value is linear across the range of 173 to 979 mmol/mol.

c. Traceability

The traceability system was established in accordance with “Committee on Diabetes Mellitus Indices of the Japan Society of Clinical Chemistry-recommended reference measurement procedure and reference materials for glycated albumin determination”. Validation of value assignment of Calibrator and Control were performed using the Manufacturer’s Product Calibrator and Control, which rank the lowest in the traceability system. Each of the Secondary Calibrators (Glycated Albumin Certified Material, JCCRM 611-1, M, H, HH) were measured and the results showed that the Calibrator and Control for Lucica[®] Glycated Albumin-L were traceable to the secondary calibrator.

d. Stability

Reagent: The shelf-life for the Lucica[®] Glycated Albumin-L reagents was 12 months when refrigerated within a temperature range between 2 and 8 °C. The open reagent stored in the Modular P reagent cabinet was stable for 1 month.

Calibrator: The shelf life for Calibrator for Lucica[®] Glycated Albumin-L was 12 months when stored at or below 8 °C. In-use stability of the Calibrator for Lucica[®] Glycated Albumin-L after reconstitution was stable for 2 weeks when stored at or below 8 °C.

Control: The shelf life for Control for Lucica[®] Glycated Albumin-L was 12 months when stored at or below 8 °C. The in-use stability of Control for Lucica[®] Glycated Albumin-L after reconstitution was set at 1 month when stored at or below 8 °C.

e. Limit of detection

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) studies of the Lucica[®] Glycated Albumin-L were performed according to CLSI Guideline EP17-A2.

The LoB, LoD, and LoQ for GA and ALB concentration were determined in the table below.

Table 4 The LoB, LoD, and LoQ for GA and ALB concentration

	Concentration of GA ($\mu\text{mol/L}$)	Concentration of albumin ($\mu\text{mol/L}$)
LoB	6.9	3.8
LoD	7.9	7.0
LoQ	9.7	21.8

f. Interference Studies

The interference study of the Lucica[®] Glycated Albumin-L was performed according to CLSI Guideline EP7-A2. To obtain high level test samples, two base serums with two GA value levels (Normal pool serum and DM serum) were spiked with high concentration stock solutions of the potential interfering substances. Control samples were obtained similarly by

adding a solvent instead of a stock solution. Next, test samples with six total different concentration levels were prepared by mixing control samples and high level test samples.

The assay was considered to have no significant interference if the bias between controls and samples containing interferent did not exceed 10%.

Table 5 Interference study of Lucica[®] Glycated Albumin-L

Compounds		Concentration of no significant interference
Endogenous compounds		
1	Unconjugated bilirubin	20.0 mg/dL
2	Conjugated bilirubin	20.0 mg/dL
3	Hemoglobin	288 mg/dL
4	Glucose	1,000 mg/dL
5	Ascorbic Acid	100 mg/dL
6	Triglycerides	1,516 mg/dL
7	Uric Acid	23.5 mg/dL

Hemoglobin at 384 mg/dL decreases the glycated albumin value in serum at 240 mmol/mol by 12.9%, and at 467 mmol/mol by 9.9%.

Triglycerides at 2,004 mg/dL decreases the glycated albumin value in serum at 232 mmol/mol by 11.6%, and at 467 mmol/mol by 2.6%.

Low and high albumin and total protein concentrations had no significant interference effect on performance of the Lucica[®] Glycated Albumin-L assay.

2. Outcomes

There is peer-reviewed literature supporting the use of glycated albumin (GA) as a good marker of glycemic control based on clinical outcomes, for microvascular complications, macrovascular complications, diabetes risk, prognosis in hemodialysis patients and predicting pregnancy outcomes. GA has been shown to be useful for the intermediate term monitoring of glycemic control in patients with diabetes.

For microvascular complications, studies involving collectively over 11,000 subjects in the US^{1), 2)} and in China³⁾, followed for 5 to 20 years revealed that GA is associated with the onset and progression of diabetic microvascular complications.

For macrovascular complications, studies in the US⁴⁾, Japan⁵⁾, Korea^{6), 7)} and China⁸⁾ involving collectively over 11,000 subjects revealed that GA is associated with vascular outcomes, atherosclerosis, poor prognosis and mortality.

3. Reference Range Study

The reference range of Lucica[®] Glycated Albumin-L for healthy non-diabetic subjects in the US was developed. The glycated albumin value in 262 healthy non-diabetic subjects ranged between 183 and 259 mmol/mol.

Conclusion

The results of performance and clinical testing demonstrate that the Lucica[®] Glycated albumin-L is substantially equivalent to glycosylated hemoglobin assays cleared under 21 CFR 864.7470 (class II; product code LCP) including the Randox Laboratories, Inc. Fructosamine assay, cleared under K023763.

References:

- 1) Nathan DM, McGee P, Steffes MW, et al. *Diabetes*. 2014; 63(1): 282-290
- 2) Selvin E et al., *Lancet Diabetes Endocrinol*. 2014; 2(4): 279-88
- 3) Pan J et al. *J Diabetes Complic*. 2014; 772-778.
- 4) Selvin E, Rawlings AM, Lutsey PL, et al. *Circulation*. 2015; 269-277
- 5) Mukai N et al., *Cardiovasc Diabetol*. 2015 Jun 24; 14: 84.
- 6) Song SO et al., *Atherosclerosis*. 2012 Dec; 225(2): 450-5.
- 7) Yoon HJ et al., *Cardiovasc Diabetol*. 2015 May 15; 14: 53.
- 8) Yang ZK, et al. *Int J Cardiol*. 2015 Oct 15; 197: 241-7.