K122101

DEC 6 2012

I. 510(k) SUMMARY

INTENDED USE AND SUMMARY OF THE PROCEDURES

The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 FLEX-PIERCING instrument. The CAPILLARYS Hb A1c kit is designed for laboratory use. Measurement of the hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The CAPILLARYS Hb A1c kit is designed for Professional Use Only.

For *In Vitro* Diagnostic Use.

The CAPILLARYS Hb A1c procedure performed with the CAPILLARYS 2 FLEX-PIERCING instrument has been certified by the National Glycohemoglobin Standardization Program (NGSP).

Electrophoresis is a well established technique routinely used in clinical laboratories for measuring components from body fluids, including HbA1c glycated fraction. The CAPILLARYS 2 FLEX-PIERCING instrument has been developed to provide complete automation of this testing with fast separation and good resolution. In many aspects, the methodology can be considered as an intermediary type of technique between classical zone electrophoresis and liquid chromatography.

The CAPILLARYS 2 FLEX-PIERCING instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow.

The CAPILLARYS 2 FLEX-PIERCING instrument has silica capillaries functioning in parallel allowing 8 simultaneous analyses for HbA1c quantification from whole blood sample. A sample dilution with hemolysing solution is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the hemoglobins is made at the cathodic end of the capillary at 415 nm, which is the absorbance wave length specific to hemoglobins. Before each run, the capillaries are washed with a wash solution and prepared for the next analysis with buffer.

Direct detection provides accurate relative quantification of individual hemoglobin A_{1c} fraction. In addition, the high resolution of CAPILLARYS Hb A1c procedure allows the quantification of HbA_{1c}, even in the presence of labile HbA_{1c}, carbamylated , acetylated hemoglobins, major hemoglobin variants such as HbS, HbC, HbD, HbE and HbF and common interfering factors such as Triglycerides, Bilirubin, Ascorbic Acid, Urea, Rheumatoid factor, and Glybenclamide as outlined in the package insert labeling.

By using alkaline pH buffer, normal and abnormal (or variant) hemoglobins are detected in the following order, from cathode to anode : A2/C, E, S/D, F, A0, other Hb (including minor Hb A1) and then A_{1c}.

SUBJECTS OF THIS 510(K) PREMARKET NOTIFICATION

This submission is limited to the CAPILLARYS Hb A1c procedure (PN 2015), CAPILARYS Hb A1c calibrators (PN 4755) and CAPILLARYS HbA1c control (PN 4744) performed with the SEBIA CAPILLARYS 2 FLEX-PIERCING instrument (PN 1227).

CAPILLARYS 2 FLEX-PIERCING is a capillary electrophoresis instrument that has been previously cleared for CAPILLARYS HEMOGLOBIN(e) assay under K112550, issued on May 25th, 2012.

REGULATORY STATUS

The CAPILLARYS Hb A1c types of devices/assays are classified by FDA as Class II, under Regulation No. 21 CFR 864.7470. SEBIA is seeking clearance to import the assay described above, and by this submission is notifying FDA of its intent to market these products in the United States.

PRODUCT DESCRIPTION

1. Reagent Kit

The CAPILLARYS HbA1c kits, controls and calibrators are used with the CAPILLARYS 2 FLEX-PIERCING system.
The configurations of the components are summarized:

- CAPILLARYS HbA1c kits in Table I.
- CAPILLARYS HbA1c Calibrators in Table II.
- CAPILLARYS HbA1c controls in Table III.
- Reagents that are required to perform the test but are sold separately in Table IV

For additional details, see Package Inserts included in Section III, Attachment III C. Each kit, control and calibrators is supplied with Package Insert which contains instruction for use and all the necessary information on the reagents needed to run the tests. Each Package Insert also contains information on storage conditions, shelf life and signs of deterioration of the components and the reagents sold separately.

TABLE I. REAGENTS AND MATERIALS SUPPLIED IN THE CAPILLARYS HbA1c KIT (PN 2015)

ITEMS	PN 2015
Buffer (ready to use)	2 vials, 700 mL each
Hemolysing solution (ready to use)	1 vial, 700 mL
Wash solution (stock solution)	1 vial, 75 mL
Green Dilution segments	1 pack of 90
Filters	4 filters

TABLE II. REAGENTS AND MATERIALS SUPPLIED WITH CAPILLARYS HbA1c CALIBRATORS (PN 4755)

ITEMS	PN 4755
Hb A1c CAPILLARYS Calibrator 1 (green cap) Hb A1c CAPILLARYS Calibrator 2 (red cap)	1 vial of each, 600µL each
Barcode label HbA1c CAPILLARYS Calibrator 1	1
Barcode label HbA1c CAPILLARYS Calibrator 2	1

TABLE III. REAGENTS AND MATERIALS SUPPLIED WITH CAPILLARYS HbA1c CONTROLS (PN 4744)

ITEMS	PN 4744
HbA1c CAPILLARYS Control 1 (white cap) HbA1c CAPILLARYS Control 2 (black cap)	1 vial of each, 600µL each
Barcode label HbA1c CAPILLARYS Control 1	2
Barcode label HbA1c CAPILLARYS Control 2	2
White Dilution segments for Control 1	4
Grey Dilution segments for Control 2	4

TABLE IV. REAGENTS AND MATERIALS REQUIRED BUT NOT SUPPLIED IN THE CAPILLARYS HbA1c KIT, CONTROLS OR CALIBRATORS

ITEMS	PN	COMPONENTS
CAPICLEAN	2058	1 vial, 25 mL
CAPILLARYS / MINICAP Wash Solution	2052	2 vials, 75 mL
Boxes for control storage	2082	2 boxes
Tubes and caps for controls	9205	500 per box
Wedge adapters	9203	10 per box
PHORESIS software	1110	
CAPILLARYS 2 FLEX-PIERCING INSTRUMENT	1227	

2. Accessories Required but Sold Separately
The accessory required for the CAPILLARYS HbA1c kit for the automated procedure has been identified in the preceding paragraphs. It is:

> CAPILLARYS 2 FLEX-PIERCING automated capillary electrophoresis system, which is part of the 510(K) premarket notification "CAPILLARYS HEMOGLOBIN(e)", K112550, for which FDA clearance was issued May 25th, 2012.

LABELING

Proposed labeling is described in Section III.

COMPARISON (CONCORDANCE), SUBSTANTIAL EQUIVALENCE AND PERFORMANCE STUDIES

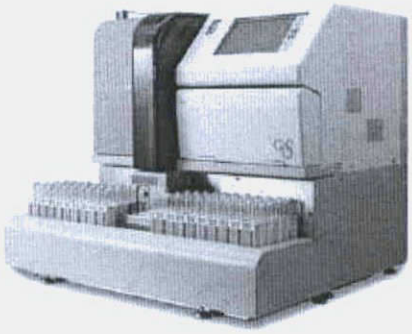
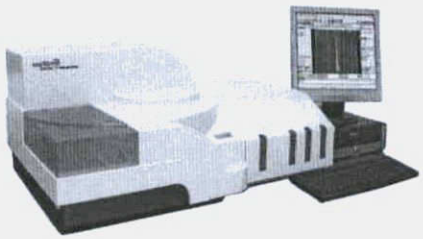
The performance and comparative studies of the CAPILLARYS Hb A1c test performed with the CAPILLARYS 2 FLEX-PIERCING system were performed using SEBIA's commercially available materials and standard procedures.

Similarly, in comparative studies, commercially available materials and standard procedures were used with the predicate device: TOSOH G8 Automated Glycohemoglobin Analyzer HLC-723G8 (K071132), which are based on high performance liquid chromatography (HPLC) of blood samples for Hb A1c analysis.

The SEBIA CAPILLARYS Hb A1c procedure, performed with the CAPILLARYS 2 FLEX-PIERCING system were found to be substantially equivalent in function, use, safety, effectiveness and the performance to predicate devices described above.

The following tables presents the similarities and the differences between the SEBIA CAPILLARYS Hb A1c test, calibrators and controls performed with the CAPILLARYS 2 FLEX-PIERCING as compared to the TOSOH G8 automated glycohemoglobin analyzer HLC-723G8 (K071132) both used for qualitative and quantitative analysis of Hb A1c .

CAPILLARYS Hb A1c using the CAPILLARYS 2 FLEX PIERCING instrument

	TOSOH G8 AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G8 (K071132)	**SEBIA CAPILLARYS Hb A1c technique with CAPILLARYS 2 FLEX-PIERCING instrument**
Intended 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. Hb A1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.	*The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human whole blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The CAPILLARYS Hb A1c kit is designed for Professional Use Only.* *For In Vitro Diagnostic Use.*
Separation System	Ion-exchange high performance liquid chromatography (HPLC): protein separation on the column based on their ionic interactions with the cartridge material and elution by buffer gradient with increasing ionic strength.Chromatograms show retention times of eluted fractions.	Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer (pH 9.4) according to their charge, to the electrolyte pH and electroosmotic flow. Fast separation and good resolution. Electrophoregrams show separated fractions according to their charge.
Instrument	TOSOH G8 instrument 	SEBIA CAPILLARYS 2 FLEX-PIERCING instrument, PN 1227 
Interface	Touch screen interface	PC interface

CAPILLARYS Hb A1c using the CAPILLARYS 2 FLEX PIERCING instrument

	TOSOH G8 AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G8 (K071132)	**SEBIA CAPILLARYS Hb A1c technique with CAPILLARYS 2 FLEX-PIERCING instrument**
Absorbance wave length	415 and 510 nm	415 nm
Software	Tosoh Piano EVO3 software	SEBIA PHORESIS™ software
Number of separation units	1 column	8 parallel capillaries (total capillaries on CAPILLARYS 2 FLEX-PIERCING instrument: 8 capillaries)
Calibration	Yes	Yes
Sample type	Whole blood in capped tube	Whole blood in capped tube
Samples identification	Yes (Bar code on sample tube)	Yes (Bar code reading on both sample racks and tubes)
Hemolysis	Performed automatically by the system	Performed automatically by the instrument
Introduction of the samples into the automatic system	Continuous loading	Continuous loading using sample racks
Analysis throughput	37 analyses / hour	40 analyses / hour
Collection tubes	Tubes with EDTA anticoagulant	Tubes with EDTA anticoagulant
Reagent	G8 Variant Elution Buffer Hsi HbA1c Calibrator set Hemoglobin A1c Control TSKgel G8 Variant Hsi Hsi Hemolysis & Wash Solution	CAPILLARYS Hb A1c Kit : Buffer Hemolyzing solution Wash solution Dilution segments Filters CAPILLARYS Hb A1c CALIBRATORS: CAPILLARYS Hb A1c Calibrator 1 CAPILLARYS Hb A1c Calibrator 2 CAPILLARYS Hb A1c CONTROLS : CAPILLARYS Hb A1c Control 1 CAPILLARYS Hb A1c Control 2
Standartization	NGSP IFCC	NGSP IFCC

CAPILLARYS Hb A1c using the CAPILLARYS 2 FLEX PIERCING instrument

The predicate device for the Hb A1c CAPILLARY calibrators is the Tosoh Hemoglobin A1c calibrators, it has been FDA cleared (K071132).

	TOSOH **Hemoglobin A1c Calibrator Set** **K071132**	**SEBIA** **HbA1c CAPILLARY CALIBRATORS**
Intended Use	The Hemoglobin A1c Calibrator Set is a reference agent designed for calibrating the Tosoh Automated Glycohemoglobin Analyzer HCL-723G8.	*The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A1c with the SEBIA CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis.* For *In Vitro* Diagnostic Use.
Format	2 levels 5 vials (4 mL) per level	2 levels 1 vial (0.6 mL) per level
Preparation	Reconstitute calibrators (1) and (2) by adding 4 mL of distilled water to each.	Reconstitute each lyophilized calibrator vial with 0.6 mL of distilled or deionized water.
Storage temperature	The Hemoglobin A1c Calibrator set should be stored at 2 to 8 °C while unopened. It will remain stable for use up to the expiration date listed on the vial.	Before reconstitution, the lyophilized calibrators must be stored between - 30 °C and - 18 °C. They are stable until the expiration date indicated on the vial labels.
In use storage	After being opened, the hemoglobin A1c Calibrator Set will remain stable for use for up to one week at 2 to 8°C.	After reconstitution, store the calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted calibrators more than 3 times.
Traceability	The assigned values are traceable to IFCC.	Same
Instrument	Tosoh Automated Glycohemoglobin Analyzer HCL-723G8	SEBIA CAPILLARYS 2 FLEX-PIERCING

The predicate device for the Hb A1c CAPILLARY controls is Tosoh Hemoglobin A1c Controls, it has been FDA cleared by the manufacturer Canterbury Scientific under (K021484).

	TOSOH **Hemoglobin A1c Controls** **K021484**	**SEBIA** **HbA1c CAPILLARY CONTROLS**
Intended Use	The Hemoglobin A1c Control are intended for use as quality control materials to monitor the precision of laboratory testing procedures for HbA1c quantitation. The controls are designed for use with Tosoh Bioscience, Inc G7and G8 analyzers.	*The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The HbA1c CAPILLARYS Controls are designed for Professional Use Only.* For *In Vitro* Diagnostic Use.
Format	2 levels 4 vials (0.25 mL) per level	2 levels 1 vial (0.6 mL) per level
Preparation	Each vial must be reconstituted with 250 µL of reagent grade type I water.	Reconstitute each lyophilized control vial with 0.6 mL of distilled or deionized water.
Storage temperature	Hemoglobin A1c controls are stable until the last day of the expiration date shown on the vial when stored unopened at 2 – 8°C.	Before reconstitution, the lyophilized controls must be stored refrigerated (2 to 8 °C). They are stable until the expiration date indicated on the vial labels.
In use storage	Once the control is reconstituted it can be used for 60 days when stored tightly capped at 2-8°C. The reconstituted control should not be stored uncapped. Aliquots can be frozen at -15°C for up to 4-6 months (no multiple thawing and re-frezing). Diluted controls should not be frozen.	After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted controls more than 30 times. After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 22 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times.
Instrument	Tosoh Automated Glycohemoglobin Analyzer HCL-723G8	SEBIA CAPILLARYS 2 FLEX-PIERCING

STANDARDS

CAPILLARYS Hb A1c test is standardized according to NGSP and IFCC requirements/guidelines (Section VII).

STATEMENT OF MANUFACTURE AND MANUFACTURING CONTROLS

The CAPILLARYS Hb A1c kits and accessories are manufactured by SEBIA in accordance with applicable GLP and GMP / Quality System practices and SEBIA's own specifications, in their entirety at its manufacturing facility located at:

Parc Technologique Léonard de Vinci,
Rue Léonard de Vinci
CP 8010 LISSES
91008 EVRY Cedex, FRANCE

All raw materials are obtained by SEBIA from qualified suppliers.

SEBIA adheres to a system of incoming, in process and finished product quality control procedures.

The manufacturing and quality control procedures are documented in Section VI of this 510(K) submission.

SEBIA has been certified against ISO 9001 / ISO 13485.

The CAPILLARYS Hb A1c devices are for *In Vitro Diagnostic Use*.

SEBIA's corporate office is located at:

Parc Technologique Léonard de Vinci,
Rue Léonard de Vinci
CP 8010 LISSES
91008 EVRY Cedex, FRANCE

Phone: (33) 1 69 89 80 80 ; Fax: (33) 1 69 89 78 78

In the United States, the product will be distributed by:

SEBIA Inc.
Suite 400 - 1705 Corporate drive
NORCROSS GA 30093, USA

Phone 770 446 – 3707 ; Fax 770 446 - 8511

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

SEBIA
c/o Karen Anderson
1705 Corporate Drive
Suite 400
Duluth, Georgia 30093

Re: k122101
Trade/Device Name: CAPILLARYS Hb Alc Kit,
Hb Alc CAPILLARY Calibrators
Hb Alc CAPILLARY Controls
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIS, JJX
Dated: November 19, 2012
Received: November 20, 2012

Dear Ms. Anderson:

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 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 Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson 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): K122101

Device Name: **CAPILLARYS Hb A1c**
using the CAPILLARYS 2 FLEX-PIERCING instrument

Indications for Use:

The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA_{1c} glycated fraction of hemoglobin in human whole blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILARYS 2 FLEX-PIERCING instrument. Measurement of hemoglobin A_{1c} is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The CAPILLARYS Hb A1c kit is designed for Professional Use Only.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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 Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122101

Indications for Use

510(k) Number (if known): K122101

Device Name: **Hb A1c CAPILLARY CALIBRATORS using the CAPILLARYS 2 FLEX-PIERCING instrument**

Indications for Use:

The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A_{1c} quantification with SEBIA CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Calibrators are designed for Professional Use Only.

Prescription Use X (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 Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122101

Indications for Use

510(k) Number (if known): K122101

Device Name: **Hb A1c CAPILLARY CONTROLS using the CAPILLARYS 2 FLEX-PIERCING instrument**

Indications for Use:

The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A_{1c} quantification with CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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510(k) K122101