510(k) Summary

OCT 12 2012

510(k) Summary of Safety and Effectiveness for the RAPIDPoint 500 System Cartridge Calibrators

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K122398

B. Date of Preparation: October 10, 2012

C. Proprietary and Established Names:
RAPIDPoint® 500 System Measurement Cartridge with Calibrators

D. Applicant:
Siemens Healthcare Diagnostics Inc., Point-of-Care Business Unit
2 Edgewater Drive
Norwood, MA 02062
Primary Contact: Amy Goldberg, Technical Specialist, Regulatory Affairs
Tel: (781) 269-3544 Fax: (781) 269-3210

Secondary Contact: Noor Malki, Vice President, Clinical, Regulatory and Quality
Tel: (781) 269-3401 Fax: (781) 269-3210

E. Regulatory Information:
1. Regulation Section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIX – calibrator, multi-analyte mixture
4. Panel: Clinical Chemistry

F. Predicate Device:
The predicate device used to demonstrate substantial equivalence is the Dimension Vista® LOCI 7 Calibrator, Models: K6456 and KC605, cleared under k100344.

G. Device Description:
The RAPIDPoint® 500 System consists of four (4) calibrators contained in the measurement cartridge and wash/waste cartridge that are used to calibrate the following analytes: pH, partial pressure of oxygen (pO_2), partial pressure of carbon dioxide (pCO_2), Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{++}), Chloride (Cl^-), Glucose (Glu), total hemoglobin (tHb) and Lactate (Lac). There is no unique calibration measurement for Neonatal Bilirubin (nBili) as the tHb calibration is used.

The measurement cartridge contains the following calibrators: 200 Cal, Reagent C and Low Sulfite Zero Cal. The wash/waste cartridge contains the wash reagent.

510(k) Summary

H. Intended Use:

The RAPIDPoint® 500 System measurement cartridge with calibrators is an *in vitro* diagnostic product for the calibration of the analytes on the RAPIDPoint® 500 System. The analytes measured are partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), pH, Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{++}), Chloride (Cl^-), Glucose (Glu), total hemoglobin (tHb), Neonatal Bilirubin (nBili) and Lactate (Lac).

I. Substantial Equivalence Information:

The RAPIDPoint® 500 System measurement cartridge with calibrators was compared to the predicate device, Dimension Vista® LOCI 7 Calibrator. The following table provides the similarities and differences

Feature	Device	Predicate Device
	RAPIDPoint® 500 System Measurement Cartridge with Calibrators	**Dimension Vista® LOCI 7 Calibrator k100344**
Intended Use	The RAPIDPoint® 500 System measurement cartridge with calibrators is an *in vitro* diagnostic product for the calibration of the analytes on the RAPIDPoint® 500 System. The analytes measured are partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), pH, Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{++}), Chloride (Cl^-), Glucose (Glu), total hemoglobin (tHb), Neonatal Bilirubin (nBili) and Lactate (Lac).	The LOCI 7 CAL is an *in vitro* diagnostic product for the calibration of Cancer Antigen 15-3 (CA 15-3) and Cancer Antigen 19-9 (CA 19-9) methods on the Dimension Vista® system.
Matrix	Aqueous salt solution	Bovine Serum Albumin
Format/Preparation	Liquid	Same
Storage/Shelf-life	Store at 2 to 8°C	Store at -25 to -15°C

510(k) Summary

J . Traceability:

Analyte	Traceability Method
pH	Traceable to NIST SRM186 reference materials via the IFCC blood reference method.
***p*CO_2**	Traceable to tonometered aqueous standards prepared using NIST traceable temperature and pressure standards and gravimetrically prepared precision gas standards.
***p*O_2**	Traceable to tonometered aqueous standards prepared using NIST traceable temperature and pressure standards and gravimetrically prepared precision gas standards.
K^+	Traceable to NIST SRM 918 reference materials using flame photometry.
Na^+	Traceable to NIST SRM 919 reference material using flame photometry.
Ca^{++}	Traceable to gravimetrically prepared internal standards using NIST SRM 915 and ISE methods embodied in Siemens blood gas analyzers.
Cl^-	Traceable to NIST SRM 919 or 918 reference materials using a Coulometric reference method.
Glucose	Traceable to NIST SRM 917 reference materials using the Hexokinase method.
tHb	Traceable to internal standards calibrated against the CLSI Cyanmethemoglobin method.
Lactate	Traceable to high purity lactate using the Lactate dehydrogenase spectrophotometric method.
Neonatal Bilirubin	There is no unique calibrator for nBili. It is an optical measurement that is associated with tHb, which is traceable as noted above.

K. Value Assignment:

Calibrator values are assigned by multiple measurements using multiple test systems such a flame photometry, mass spectrometry and others.

L. Stability:

The stability protocols and acceptance criteria were included and testing data met predetermined acceptance criteria. The following table lists the stability/shelf life for each calibrator:

Calibrator	Stability/Shelf Life
200 Cal	12 months at 2° to 8°C
Low Sulfite Zero Cal (LSZC)	12 months at 2° to 8°C
Reagent C	15 months at 2° to 30°C

M. Performance Characteristics:

The calibrator target levels, protocol, value assignment procedure, acceptance criteria, stability and traceability for the following analytes: pH, partial pressure of oxygen (pO_2), partial pressure of carbon dioxide (pCO_2), Sodium, (Na^+), Potassium (K^+), ionized Calcium (Ca^{++}), Chloride (Cl^-), Glucose (Glu) , total hemoglobin (tHb) and Lactate (Lac) have been validated following procedures of Siemens Healthcare Diagnostics Inc. Point-of-Care Business Unit. There is no unique calibration measurement for nBili as the tHb calibration is used.

N. Conclusion:

The RAPIDPoint® 500 System measurement cartridge with calibrators is substantially equivalent to the Dimension Vista® LOCI 7 Calibrator previously cleared under k100344.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Amy Goldberg
2 Edgewater Drive
Norwood, MA 02062

OCT 12 2012

Re: k122398
Trade Name: RAPIDPoint® 500 System Measurement Cartridge with Calibrators
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX
Dated: August 6, 2012
Received: August 7, 2012

Dear Ms. Goldberg:

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); 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).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices 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 postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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 H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k122398

Device Name: RAPIDPoint® 500 System Measurement Cartridge with Calibrators

Intended Use:

The RAPIDPoint® 500 System measurement cartridge with calibrators is an *in vitro* diagnostic product for the calibration of the analytes on the RAPIDPoint® 500 System. The analytes measured are partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), pH, Sodium (Na^+), Potassium (K^+), ionized Calcium (Ca^{++}), Chloride (Cl^-), Glucose (Glu), total hemoglobin (tHb), Neonatal Bilirubin and Lactate (Lac).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yueng Chan

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

510(k) ____K122398_____