K110277

510(k) Summary - Revised

AUG 15 2011

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter information

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Date summary prepared:	July 11, 2011

Device Information

Proprietary Name:	RAPIDPoint® 405 System Neonatal Bilirubin (nBili) Test
Common name:	Neonate bilirubin on blood gas system
Classification name:	Bilirubin in the neonate test system
Classification number:	21 CFR 862.1113, Class I, reserved, MQM
Classification panel:	Clinical Chemistry and Clinical Toxicology Devices

Predicate Device

Element	Predicate Device
Device Name	Neonatal Bilirubin on RAPIDLab® 1200 Blood Gas System
Common Name	Neonate bilirubin on blood gas system
510(k) Number	K073537
Manufacturer	Siemens Healthcare Diagnostics Limited

Device Description

Neonatal Bilirubin (nBili) is a new parameter offered on the RAPIDPoint 405 (RP405) blood gas system. The RP405 system is a point of care and laboratory testing blood gas analyzer and currently measures a variety of parameters that have been previously cleared. Enabling the nBili measurement is accomplished through software design changes introduced in Software Version 3.7. No hardware or mechanical changes were needed.

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The nBili test is intended for in vitro diagnostic use by healthcare professionals for the determination of total neonatal bilirubin concentration in the whole blood samples of newborn infants. Measurement of nBili aids in assessing the risk of kernicterus.

Statement of Intended Use

The neonatal bilirubin test used on RAPIDPoint® 405 systems is an *in vitro* diagnostic test for the determination of total neonatal bilirubin (nBili) concentration in the whole blood of newborn infants. Measurement of nBili aids in assessing the risk of kernicterus. This test is intended for use in point of care or laboratory settings.

Summary of Technological Characteristics

The RAPIDPoint 405 system uses multiple wavelength spectrophotometry (CO-oximetry) to measure the transmission of light through a sample of neonate whole blood to determine concentrations of hemoglobin derivatives and bilirubin.

The RAPIDPoint 405 system aspirates the whole blood sample at the sample port and then transfers the sample to the CO-ox sample chamber. As the sample flows through an optical chamber, the CO-ox optics head directs light through the sample and to a polychromator that measures the intensity of transmitted light at different wavelengths.

Iterative least squares analysis is used to determine raw bilirubin values. Raw values are then corrected for hematocrit to produce nBili results.

Assessment of Performance

Studies were conducted to demonstrate the performance of the RAPIDPoint 405 with nBili parameter and assess substantial equivalence against the Siemens Healthcare Diagnostics RAPIDLab 1245 and 1265 (predicate device).

The nBili internal evaluation study entailed testing concentrations of unconjugated bilirubin in oxygenated cord whole blood (which mimics neonatal samples) across the reporting ranges. The nBili external evaluation study included testing at multiple point of care sites with intended use neonatal whole blood samples. Combining these internal and external evaluations for a total of approximately 200 samples, the correlation coefficient (r) value was within the acceptance criteria (>0.90). Specimens were evaluated against the RAPIDLab 1245 and 1265 predicate devices and based on performance data analyzed, it was concluded that the predetermined acceptance criteria were met.

In addition, information on Software Development Life Cycle including software requirements specifications, risk management report, and overall verification and validation results were included to provide additional assurance of device performance.

Conclusion

In conclusion, the studies completed demonstrate that the RAPIDPoint® 405 System Neonatal Bilirubin (nBili) Test is similar to the RAPIDLab 1245 and 1265 predicate device in both Technological Characteristics and Intended Use. The data presented in the submission is a summary of internal evaluation, external clinical evaluation, and software development information. This information provides assurance that the RAPIDPoint 405 system measuring neonate bilirubin has demonstrated substantial equivalence to the currently marketed Siemens Healthcare Diagnostics RAPIDLab 1245 and 1265 predicate device across the reporting range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Steven Goldberg
2 Edgewater Drive
Norwoord, MA 02062

Re: k110277
Trade Name: Siemens Healthcare Diagnostics, RAPIDPoint® 405 System Neonatal Bilirubin (nBili) Test
Regulation Number: 21 CFR §862.1113
Regulation Name: Bilirubin in the Neonate Test System
Regulatory Class: Class I, reserved
Product Codes: MQM
Dated: July 11, 2011
Received: July 12, 2011

AUG 15 2011

Dear Mr. 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety 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,

Courtney Harper, Ph.D.
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 Form

510(k) Number (if known): K110277

Device Name: RAPIDPoint® 405 System

Intended Use:

The RAPIDPoint 405 system is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- Partial pressure of carbon dioxide
- Partial pressure of oxygen
- pH
- Sodium
- Potassium
- Ionized calcium
- Chloride
- Glucose
- Total hemoglobin and fractions: fO_2Hb, fCOHb, fMetHb, fHHb
- Neonatal bilirubin

This test system is intended for use in point of care or laboratory settings.

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)

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The following list includes the **Indications for Use** information for each analyte measured on the Rapidpoint 405 System:

pCO_2, $p0_2$, pH. Measurements of blood gases (pCO2, p02) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Neonate Bilirubin. A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

Sodium. Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium. Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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

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Glucose. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Total hemoglobin. Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin. Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin. Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

Sulfhemoglobin. Sulfhemoglobin measurements are used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison).

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

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