510(k) Summary

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

1.0 Submitter Information

Owner
Siemens Healthcare Diagnostics, Inc.
Point of Care (POC) Business Unit
2 Edgewater Drive
Norwood, MA 02062

Contact
Primary: Amy Goldberg
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781-269-3544 TEL

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Date Summary Prepared
March 21, 2013

2.0 Device Information

Proprietary Name
RAPIDPoint® 400/405/500 Systems

Common Name
Pleural Fluid pH

Main Classification Name
Blood gases (PCO2, PO2) and blood pH test system
21 CFR 862.1120, Class II
Product Code CHL

3.0 Predicate Device

<table>
<thead>
<tr>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
</tr>
<tr>
<td>Common Name</td>
</tr>
<tr>
<td>510(k) Number</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

4.0 Device Description

The RP400/405/500 system is a point-of-care and laboratory testing blood gas analyzer and currently measures a variety of parameters. With this planned release of software, the ability to measure pH in Pleural Fluid will be added to the system.
The pleural fluid pH measurement provides important information for the diagnosis of exudative pleural effusions. The RAPIDPoint® 400/405/500 system is intended for in vitro testing of pleural fluid samples for the pH parameter. This test system is intended for use in point of care or laboratory settings.

Pleural fluid pH testing follows the same principles as whole blood pH testing. The notation of pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration. The pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology.

5.0 Intended Use Statement
RAPIDPoint® 400/405/500 systems are intended for in vitro testing of pleural fluid samples for the pH parameter. Test systems are intended for use in point of care or laboratory settings.

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.

6.0 Summary Comparison of Technological Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>RAPIDPoint® 400/405/500 Pleural Fluid pH (Modified Device)</th>
<th>ABL835 FLEX Analyzer With Pleural pH (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>RAPIDPoint® 400/405/500 systems are intended for in vitro testing of pleural fluid samples for the pH parameter. Test systems are intended for use in point of care or laboratory settings.</td>
<td>Same without point of care testing.</td>
</tr>
<tr>
<td></td>
<td>The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The following critical value applies to pleural fluid pH: pH &gt; 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement &lt; 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.</td>
<td></td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>Blood gas analyzer</td>
<td>Same</td>
</tr>
<tr>
<td>Test Principle</td>
<td>Potentiometric</td>
<td>Same</td>
</tr>
<tr>
<td>Measured Parameter</td>
<td>pH in Pleural Fluid</td>
<td>Same</td>
</tr>
</tbody>
</table>
### 6.0 Summary Comparison of Technological Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>RAPIDPoint® 400/405/500 Pleural Fluid pH (Modified Device)</th>
<th>ABL835 FLEX Analyzer With Pleural pH (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter Nomenclature</td>
<td>pH in Pleural Fluid</td>
<td>Same</td>
</tr>
<tr>
<td>Technology</td>
<td>Pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology</td>
<td>Same</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Pleural Fluid</td>
<td>Same</td>
</tr>
<tr>
<td>Expected Values*†‡</td>
<td>The following critical value applies to pleural fluid pH: pH &gt; 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement &lt; 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.</td>
<td>Same</td>
</tr>
<tr>
<td>Reported Output</td>
<td>pH units</td>
<td>Same</td>
</tr>
<tr>
<td>Reporting Range</td>
<td>7.000 to 7.500</td>
<td>Same</td>
</tr>
<tr>
<td>Calibration</td>
<td>2 point calibration using automated on-board reagent</td>
<td>2 point liquid calibration</td>
</tr>
<tr>
<td>Main Test Steps</td>
<td>Select ‘Pleural Fluid’ button. Collect sample, insert device into sample luer, &amp; select “Start”</td>
<td>Same (‘Other Fluids’ button)</td>
</tr>
</tbody>
</table>


### 7.0 Test Principle

Pleural fluid pH testing follows the same principles as whole blood pH testing. The notation of pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration. The pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology.

### 8.0 Performance Characteristics

**Analytical Performance**

a. Precision / Reproducibility

The Precision study consisted of two runs per day, an n=2 per sample run on the RP400/405/500 and performed over the course of 20 days for an n of 80. Pleural fluid samples were buffered and the tension of CO₂ altered to three levels of pH within 7.0 to 7.5 units. All were then stored frozen until the time of use.

Each run performed in Pleural Fluid mode and spaced a minimum of two hours apart, contained Calibration Verification Material (CVM) and pleural fluid samples. Complete QC
Level 2 was analyzed within the center of each run to verify instrument performance. Results for CVM controls and pleural fluid pH are contained in the tables below:

### Precision with Controls

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>Mean</th>
<th>WRSD*</th>
<th>% WRCV</th>
<th>Total SD†</th>
<th>% Total CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP400</td>
<td>2</td>
<td>80</td>
<td>7.091</td>
<td>0.003</td>
<td>0.004</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>80</td>
<td>7.312</td>
<td>0.002</td>
<td>0.002</td>
<td>0.0</td>
</tr>
<tr>
<td>RP405</td>
<td>2</td>
<td>80</td>
<td>7.102</td>
<td>0.004</td>
<td>0.004</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>80</td>
<td>7.327</td>
<td>0.002</td>
<td>0.003</td>
<td>0.0</td>
</tr>
<tr>
<td>RP500</td>
<td>2</td>
<td>80</td>
<td>7.098</td>
<td>0.002</td>
<td>0.004</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>80</td>
<td>7.324</td>
<td>0.002</td>
<td>0.004</td>
<td>0.0</td>
</tr>
</tbody>
</table>

### Precision with Pleural Fluid

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>Mean</th>
<th>WRSD*</th>
<th>% WRCV</th>
<th>Total SD†</th>
<th>% Total CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP400</td>
<td>Low</td>
<td>80</td>
<td>7.102</td>
<td>0.010</td>
<td>0.011</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>80</td>
<td>7.284</td>
<td>0.010</td>
<td>0.011</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>80</td>
<td>7.469</td>
<td>0.007</td>
<td>0.008</td>
<td>0.1</td>
</tr>
<tr>
<td>RP405</td>
<td>Low</td>
<td>80</td>
<td>7.102</td>
<td>0.009</td>
<td>0.011</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>80</td>
<td>7.289</td>
<td>0.012</td>
<td>0.012</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>80</td>
<td>7.473</td>
<td>0.007</td>
<td>0.007</td>
<td>0.1</td>
</tr>
<tr>
<td>RP500</td>
<td>Low</td>
<td>80</td>
<td>7.080</td>
<td>0.006</td>
<td>0.016</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>80</td>
<td>7.260</td>
<td>0.011</td>
<td>0.018</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>80</td>
<td>7.450</td>
<td>0.011</td>
<td>0.019</td>
<td>0.3</td>
</tr>
</tbody>
</table>

* WRSD = within-run standard deviation
% WRCV = percent within-run coefficient of variation
† Total SD = total standard deviation
% Total CV = percent total coefficient of variation

The sponsor performed a Precision study using typical point of care (POC) operators at three sites running pleural fluid samples on the RP400/405/500 systems. The testing was performed in Pleural Fluid mode over a minimum of 1 day, 3 runs per day, with each run separated by two hours to simulate several days and 5 replicates per run for each of the three levels across the reportable pleural fluid pH range (Low, Mid, High) for a total N = 45. All pleural fluid samples were stored frozen at -70°C or below individually until the time of use. Results are contained in the table below:
**Precision with Pleural Fluid (Point of Care Study – Three Sites)**

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>Mean</th>
<th>WRSD*</th>
<th>% WRCV</th>
<th>Total SD†</th>
<th>% Total CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP400</td>
<td>Low</td>
<td>45</td>
<td>7.121</td>
<td>0.014</td>
<td>0.19</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>45</td>
<td>7.295</td>
<td>0.012</td>
<td>0.16</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>45</td>
<td>7.464</td>
<td>0.019</td>
<td>0.26</td>
<td>0.02</td>
</tr>
<tr>
<td>RP405</td>
<td>Low</td>
<td>45</td>
<td>7.110</td>
<td>0.019</td>
<td>0.26</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>45</td>
<td>7.289</td>
<td>0.011</td>
<td>0.15</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>45</td>
<td>7.463</td>
<td>0.017</td>
<td>0.23</td>
<td>0.02</td>
</tr>
<tr>
<td>RP500</td>
<td>Low</td>
<td>45</td>
<td>7.109</td>
<td>0.013</td>
<td>0.19</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>45</td>
<td>7.285</td>
<td>0.013</td>
<td>0.18</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>45</td>
<td>7.463</td>
<td>0.014</td>
<td>0.18</td>
<td>0.02</td>
</tr>
</tbody>
</table>

* WRSD = within-run standard deviation
† Total SD = total standard deviation
% WRCV = percent within-run coefficient of variation
% Total CV = percent total coefficient of variation

b. Detection Limit

Detection limit for pleural fluid pH was established in the method comparison study, Section e. below, and for whole blood pH in the previously cleared submission (K002738). The measuring range for pleural fluid pH samples is 7.0 to 7.5.

c. Analytical Specificity

Analytical specificity was established in the previously cleared submission (K002738).

d. Linearity/assay reportable range

Linearity data for pleural fluid collected in the comparison study (see Section e. Method Comparison Studies below) was used to demonstrate linearity on the RP400/405/500 analyzer. Linear regression analysis of the results yielded the following:

- **RP400**: $y = 1.066x (-0.437), r^2 = 0.99$
- **RP405**: $y = 1.008x (-0.009), r^2 = 0.95$
- **RP500**: $y = 1.059x (-0.373), r^2 = 0.99$

**Comparison Studies**

e. Method Comparison with Predicate Device

The sponsor performed method comparison studies at 3 point of care (POC) clinical sites using at least 3 typical POC operators and one RP405 instrument per site vs. the ABL835 FLEX predicate device. Multiple cartridges and reagent lots were used for this study. All sites were data collection (testing) sites. All specimens were de-identified, leftover samples, collected both prospectively and retrospectively. Less than 20% of the samples...
in the study were altered samples. Linear regression analysis was used to determine the coefficient of determination ($r^2$) and to determine the slope and intercept. The results for the RP405 vs. the predicate device met the acceptance criteria and are contained in the table below:

**Statistical Summary of RP405 vs. an ABL 835 FLEX System**

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>RMSE</th>
<th>$r^2$</th>
<th>Sample Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>142</td>
<td>1.008</td>
<td>-0.009</td>
<td>0.030</td>
<td>0.95</td>
<td>7.000 – 7.466</td>
</tr>
</tbody>
</table>

RMSE = Root Mean Square Error  
$r^2$ = Coefficient of Determination

The sponsor performed an additional Method Comparison study using typical POC operators at three sites with a minimum of 40 pleural fluid samples per site run in duplicate across the pleural fluid pH reporting range of 7.0 to 7.5 on the RP400 and RP500 vs. the ABL835 FLEX predicate device. Linear regression analysis was used to determine the coefficient of determination ($r^2$) and to determine the slope and intercept. The results for the RP400 and RP500 vs. the predicate device met the acceptance criteria and are contained in the table below:

**Statistical Summary of RP400, RP500 vs. an ABL 835 FLEX System**

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>RMSE</th>
<th>$r^2$</th>
<th>Sample Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP400</td>
<td>122</td>
<td>1.066</td>
<td>-0.437</td>
<td>0.014</td>
<td>0.99 7.011 – 7.458</td>
</tr>
<tr>
<td>RP500</td>
<td>122</td>
<td>1.059</td>
<td>-0.373</td>
<td>0.016</td>
<td>0.99 7.011 – 7.452</td>
</tr>
</tbody>
</table>

RMSE = Root Mean Square Error  
$r^2$ = Coefficient of Determination

f. Matrix Comparison  
Not applicable.

**Clinical Studies**

g. Clinical Sensitivity  
Not applicable

h. Clinical Specificity  
Not applicable

**Clinical Cut-off**  
Not applicable

**Expected Values *††/ Reference Range**

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.
9.0 **Instrument Name:**
RAPIDPoint 400/405/500 Blood Gas Analyzer

10.0 **System Descriptions**

*Modes of Operation*

Pleural Fluid (PF) pH is a new sample type offered on the RAPIDPoint® 400/405/500 (RP400/405/500) blood gas system. The RP400/405/500 system is a point-of-care and laboratory testing blood gas analyzer. Single testing.

**Specimen Identification**

Samples are identified by barcode.

**Specimen Sampling and Handling**

Users follow the same sample handling process already in place for measuring other parameters on the blood gas analyzer. Users can analyze samples using the sample collection devices and pleural fluid is collected in a syringe.

**Calibration**

There is no unique calibration measurement for pleural fluid pH. The pH calibration measurement is used for pleural fluid pH. The targeted calibration points for pH are:

- Calibration Point: 6.8
- Slope Point: 7.4

**Quality Control**

No unique RapidQC® Complete or CVM® control materials are required for pleural fluid pH. The AutomaticQC cartridge available with the release of the System Software version 3.8 (2.1 on RP500) supports the use of pleural fluid pH.

No new or modified Quality Control (QC) procedures are required to measure pleural fluid pH. The external quality controls, RAPID QC Complete, used in validation are commercially available and were cleared under the 510(k) number K970956.

*Other Supportive Instrument Performance Characteristics Data Not Covered in the “Performance Characteristics” Section above:*

None
11.0 Conclusion

The results of these studies demonstrate that the RAPIDPoint 400/405/500 blood gas analyzer is similar to the predicate in both Technological Characteristics and Intended Use and is therefore substantially equivalent. The data presented is a summary of external clinical evaluation, internal laboratory evaluation, and software development information. The RAPIDPoint 400/405/500 performance was shown to be substantially equivalent to the predicate device.
April 19, 2013

Siemens Healthcare Diagnostics, Inc.
C/O Amy Goldberg
Point of Care (POC) Business Unit
2 Edgewater Drive
NORWOOD MA 02062

Re: K122539
   Trade/Device Name: RAPIDPoint® 400/405/500 Systems
   Regulation Number: 21 CFR 862.1120
   Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
   Regulatory Class: II
   Product Code: CHL
   Dated: March 21, 2013
   Received: March 22, 2013

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. 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 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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -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): k122539

Device Name: RAPIDPoint® 400/405/500 Systems

Indications for Use:

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The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.

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)

Yung Chan -S

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

510(k) K122539

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