K101947

SPHERE
RAISING THE STANDARD OF CRITICAL CARE

**IVD-GE02 510(k) Submission**

Reference
REP059

# 510(k) SUMMARY

MAR 16 2011

As requested by 21 CFR 807.92, the following 510(k) summary is provided:

## SUBMITTER'S INFORMATION


Submitter's Name and Address: Sphere Medical Ltd.
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Contact Person: Mary Hutchens
Regulatory Affairs Manager


## DEVICE INFORMATION

Proprietary Name: IVD-GE02

Common Name: Blood Analyser

Classification:

| NAME | CLASS | REGULATION NUMBER | PANEL | PRODUCT CODE |
|---|---|---|---|---|
| Electrode, Measurement of Blood Gasses (pO2, pCO2 ) and Blood pH | II | 862.1120 | Clinical Chemistry | CHL |
| Electrode, Ion Specific Potassium | II | 862.1600 | Clinical Chemistry | CEM |
| Glucose oxidase, Glucose | II | 862.1345 | Clinical Chemistry | CGA |
| Calibrators | II | 862.1150 | Clinical Chemistry | JIX |

## PREDICATE DEVICE INFORMATION

| | |
|---|---|
| **NAME** | Rapidlab 865 |
| **MANUFACTURER** | Siemens Healthcare Diagnostics |
| **510(K) NUMBER** | K934907 |

## DESCRIPTION OF DEVICE

The IVD-GE02 system is an *in-vitro* diagnostic device for the determination of specified analytes in blood using electrochemical principles. The IVD-GE02 is essentially a modular system consists of the following components:-

- A dedicated combined PC and monitor with a touch screen
- A disposable cartridge containing
  - Sensor
  - Electronic circuitry, including an ASIC (Application Specific Integrated Circuit), to process sensor signals and drive the fluid management system.
- An instrument containing
  - Fluid management components (tubing, pumps and valves)
  - The cartridge (see above)
  - An injection port for samples, calibration solutions and QC solutions
  - Wiring to connect the cartridge to the fluid management components
- Syringes with calibration solutions packed in sealed foil bags
- Containers with flush solutions
- A waste container
- A dedicated printer and associated cables
- An ambient temperature and pressure sensor
- Cables to connect the monitor to the instrument and a power supply unit
- Packaging
- Label Copy

## INTENDED USE OF THE DEVICE

Indications for Use:

The IVD-GE02 system is a blood gases analyzer intended as an in vitro diagnostic device for the quantitative measurement of whole blood samples in a clinical laboratory. The IVD-GE02 system includes sensors for the measurement of pH, $pCO_2$, $pO_2$, potassium and glucose.

**pH, $pCO_2$, $pO_2$.** Measurement of blood gases ($pCO_2$, $pO_2$) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

**Potassium.** Measurement of potassium are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by high or low potassium levels.

**Glucose**. Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathetic hypoglycaemia and of pancreatic islet cell carcinoma.

**IVD-GE02 calibration solutions** are in vitro diagnostic products for the calibration of the IVD-GE02 test system for the measurements of pH, pCO2, pO2, potassium and glucose.

SIMILARITIES AND DIFFERENCES TO PREDICATE DEVICES

| CHARACTERISTIC | IVD-GE02 | RAPIDLAB 865<br>K934907 |
|---|---|---|
| Intended Use | For use by trained healthcare professionals in a clinical laboratory | For use by trained healthcare professionals in a clinical laboratory |
| Measured Parameters | pH, $pCO_2$, $pO_2$, $K^+$,Glucose | pH, $pCO_2$, $pO_2$, $Na^+$, $K^+$, $Ca^{++}$, Glucose, Lactate, $Cl^-$, tHb, FHHb,$FO_2Hb$, FMetHb,.FCOHb |
| Sample Type | Whole blood | Whole blood |
| Sensor Array | Multi-analyte chip | Individual sensors |
| Test principle | Electrochemical (potentiometric, amperometric) | Electrochemical (potentiometric, amperometric), biochemical, optical |
| **Individual test sensor type** | | |
| pH | Potentiometric ISFET | Potentiometric<br>ISE |
| $pCO_2$ | Potentiometric<br>ISFET | Potentiometric<br>ISE |
| $pO_2$ | Amperometric | Amperometric |
| $K^+$ | Potentiometric<br>ISFET | Potentiometric<br>ISE |
| Glucose | Amperometric | Amperometric |
| **Calibrators** | | |
| | Aqueous solutions | Aqueous solutions |
| | Two level target calibration | Two level target calibration |
| | Contains sodium, potassium, calcium, surfactant, buffer (phosphate), glucose and dissolved,$O_2$, $CO_2$.. | Contains sodium, potassium, chloride, surfactant, buffer, glucose. $O_2$, $CO_2$ gas. |
| | Stored at 15°C - 25 °C | Stored at 4°C - 25 °C |
| | | |

## TECHNOLOGICAL CHARACTERISTICS

The IVD-GE02 system is contained on a single multi-analyte sensor chip that has an array of individual sensors, each of which measures a different analyte. The sensors produce electrical signals in response to the analytes in the blood. The signal from each sensor is proportional to the concentration of analyte.

The individual sensors use one of two transducer technologies: potentiometric (a field effect transistor structure to measure the potential generated), and amperometric (measuring the current generated).

Many of the transducers on the sensor chip require a covering membrane so that they can respond to a specific analyte. The membranes used by Sphere on the IVD- GE02 sensor array are based on those already used in other commercially available blood analysers.

### Performance Data Summary

### Linearity

The study design was based on CSLI document EP6-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"

The study used human whole blood as the test material and was conducted for the analytes pH, *p*CO2, *p*O2, K+, and glucose.
7 levels of each analyte were read in duplicate on each of three IVD-GE02 systems and the predicate device (Rapidlab 865 blood gas analyser).

| Analyte | Test Range | Units | $R^2$ |
|---|---|---|---|
| pH | 6.8 – 7.8 | N/A | >0.99 |
| $pO_2$ | 28 – 498 | mmHg | >0.99 |
| $pCO_2$ | 21.8 – 101.9 | mmHg | >0.99 |
| $K^+$ | 2.1 – 9.7 | mM | >0.99 |
| Glucose | 10.8 – 445.3 | m/dL | >0.99 |

## Aqueous Precision

### Method

The study design is based on CLSI document EP5-A2. Evaluation of Precision Performance of Quantitative Measurement Methods Approved Guideline-Second Edition. On each day the outlier test was applied to the duplicate readings, as described in EP5-A2. Data was analysed as specified in CLSI guideline EP5-A2.

The mean, the repeatability (within run precision), the between-day standard deviation, the between-run standard deviation and the total precision were calculated from the raw data with all calculations being performed as recommended in CLSI guideline EP5-A2.

The precision data collected for the IVD-GE02 shows comparable performance to published precision data for other blood analysers within the reference range.

## Precision in Blood

### Method.

The study was conducted for the analytes pH, $pCO_2$, $pO_2$, $K^+$, and glucose and for each analyte, human blood samples were prepared at two different levels of analyte. Ten readings of the analyte level in human blood were taken at each analyte level. After each replicate of a blood sample was read on the IVD-GE02 system the same sample was read on the predicate device (Rapidlab 865 blood gas analyser).

Human whole blood was used for the "Precision Study in Blood". Blood was drawn into heparinised vacutainers by trained phlebotomists. All blood was used within 24 hours of donation.

## Results

**Summary of pH precision in blood data**

| | Blood 1<br>IVD-GE02<br>Monitor 2 | Blood 2<br>IVD-GE02<br>Monitor 4 |
|---|---|---|
| Mean (pH units) | 7.355 | 7.242 |
| Standard deviation | 0.018 | 0.014 |
| Coefficient of variation (%CV) | 0.242 | 0.200 |

**Summary of K+ precision in blood data**

| | Blood 1<br>IVD-GE02<br>Monitor 2 | Blood 2<br>IVD-GE02<br>Monitor 5 |
|---|---|---|
| Mean (mM $K^+$) | 4.10 | 6.65 |
| Standard deviation | 0.08 | 0.21 |
| Coefficient of variation (%CV) | 1.99 | 3.17 |

**Summary of oxygen precision in blood data**

| | Blood 1<br>IVD-GE02 Monitor 4 | Blood 2<br>IVD-GE02 Monitor 7 |
|---|---|---|
| Mean (mmHg $O_2$) | 30.4 | 91.3 |
| Standard deviation | 0.8 | 2.3 |
| Coefficient of variation (%CV) | 2.7 | 2.5 |

**Summary of glucose precision in blood data (mM)**

| | Blood 1<br>IVD-GE02<br>Monitor 2 | Blood 2<br>IVD-GE02<br>Monitor 5 |
|---|---|---|
| Mean (mM glucose) | 4.9 | 11.9 |
| Standard deviation | 0.19 | 0.26 |
| Coefficient of variation (%CV) | 3.9 | 2.2 |

**Summary of glucose precision in blood data (mg/dL)**

| | Blood 1<br>IVD-GE02<br>Monitor 2 | Blood 2<br>IVD-GE02<br>Monitor 5 |
|---|---|---|
| Mean (mM glucose) | 88.4 | 215.0 |
| Standard deviation | 3.44 | 4.75 |
| Coefficient of variation (%CV) | 3.9 | 2.2 |

**Summary of CO2 precision in blood data**

| | Blood 1<br>IVD-GE02<br>Monitor 4 | Blood 2<br>IVD-GE02<br>Monitor 7 |
|---|---|---|
| Mean (mmHg $CO_2$) | 39.3 | 68.3 |
| Standard deviation | 2.60 | 1.66 |
| Coefficient of variation (%CV) | 6.61 | 2.42 |

## METHOD COMPARISON

The Method Comparison study compared the IVD-GE02 with the Rapidlab 865 predicate device. The study was conducted in a clinical setting with human blood samples. Data from the linearity study was also included to extend the analyte range used.

### Method

The objective of the study was to compare the IVD-GE02 system and the Rapidlab 865 blood gas analyser for measurements on human blood of pH, potassium, oxygen, glucose and carbon dioxide.

The study design is based on the CSLI guideline EP9A-2 and a review of similar 510(k) submissions.

### Summary Results Table

| Analyte | N | Slope (calculated by Deming regression) | Intercept (calculated by Deming regression) | $R^2$ (calculated using least squares linear regression) | Sample range tested |
|---|---|---|---|---|---|
| pH (pH units) | 104 | 1.04 | -0.26 | 0.9954 | 6.815-7.797 |
| pCO2 (mmHg) | 102 | 1.03 | -1.00 | 0.9501 | 20.8-100 |
| pO2 (mmHg) | 105 | 0.97 | 3.66 | 0.9917 | 38.7-496.9 |
| $K^+$ (mmol/L) | 111 | 1.00 | 0.29 | 0.9523 | 2.5-8.9 |
| Glucose (mg/dL) | 98 | 0.96 | 8.69 | 0.9559 | 48.6-397.8 |

## INTERFERENT STUDY

The study design is based on CLSI document EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline Second Edition and was designed to ascertain the effect of potential interfering substances of the performance of the IVD-GE02

**Compounds showing an interferent effect on IVD-GE02 readings**

| Analyte | Interferent | Concentration of Interferent Tested |
|---|---|---|
| pH | Acetyl salicylic acid | 2170µM |
| $pO_2$ (levels ≤ 22mmHg) | Halothane | ≥253 µM |
| $pCO_2$ | Sodium pentothal | 20.6 µM |
| Potassium | Sodium pentothal | ≥248 µM |
| Glucose | Acetaminophen | 662 µM |
| | $O_2$ | ≤ 30mmHg |
| | Triglyceride | ≥15mM |

## Conclusions

For all analytes the observed precision, linearity and method comparison of the IVD-GE02 system is substantially equivalent to that seen for the predicate device (Rapidlab 865).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

MAR 16 2011

Sphere Medical Ltd.
c/o Ms. Mary Hutchens
Regulatory Affairs Manager
Harston Mill, Harston
Cambridge, CB22 7GG, United Kingdom

Re: k101947
Trade Name: IVD-GE02
Regulation Number: 21 CFR §862.1120
Regulation Name: Blood Gases (pCO2, pO2) and Blood pH Test System.
Regulatory Class: Class II
Product Codes: CHL, CEM, CGA, JIX
Dated: February 4, 2011
Received: February 7, 2011

Dear Ms. Hutchens:

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): __K101947____

Device Name: _____IVD-GE02_____

Indications for Use:

The IVD-GE02 system is a blood gases analyzer intended as an in vitro diagnostic device for the quantitative measurement of whole blood samples in a clinical laboratory. The IVD-GE02 system includes sensors for the measurement of pH, $pCO_2$, $pO_2$, potassium and glucose.

pH, $pCO_2$, $pO_2$: Measurement of blood gases ($pCO_2$, $pO_2$) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium: Measurement of potassium are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by high or low potassium levels.

Glucose: Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathetic hypoglycaemia and of pancreatic islet cell carcinoma.

IVD-GE02 calibration solutions are in vitro diagnostic products for the calibration of the IVD-GE02 test system for the measurements of pH, pCO2, pO2, potassium and glucose.

| Prescription Use ___√____ (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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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

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

510(k) K101947