Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K192240

B Applicant

Siemens Healthcare Diagnostics, Inc.

C Proprietary and Established Names

RAPIDPoint® 500e Blood Gas System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CHL	Class II	21 CFR 862.1120 - Blood gases (*p*CO2, *p*O2) and Blood pH Test System	CH - Clinical Chemistry
JGS	Class II	21 CFR 862.1665 - Sodium Test System	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 -Potassium Test System	CH - Clinical Chemistry
JFP	Class II	21 CFR 862.1145 - Calcium Test System	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride Test System	CH - Clinical Chemistry
CGA	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
GKR	Class II	21 CFR 864.5620 -Total hemoglobin Test System	CH - Clinical Chemistry
MQM	Class I reserved	21 CFR - 862.1113 Bilirubin in the neonate Test System	CH - Clinical Chemistry
KHP	Class I	21 CFR 862.1450 - Lactic Acid Test System	CH - Clinical Chemistry

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own: CLASS II, device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device are RAPIDPoint 500 System and K122539.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. The changes included the following:**

    - A design change was made to update the Operating System (OS) software from Microsoft Windows 7 Embedded to Windows 10 IoT (internet of Things).
    - Upgraded Barcode to support external and onboard 1D and 2D barcode scanners.
    - Updated selected instrument main board parts due to obsolescence:
        - EXT (Embedded Technology Extended)
        - FPGA (Field Programmable Gate Array)
        - CPLD (Complex programmable Logic Device)
    - Solid state Hard Drive will have a different model due to obsolescence.
    - Sodium sensor interferent detected message
    - Encrypted data transmission with POCcelerator (Cybersecurity enhancement)
    - USB port ON/OFF capability
    - Required QC after cartridge change
    - Notification when (Automatic quality control) AQC is disabled.
    - AQC automatic printing.
    - Restricted QC override.
    - Updated exterior and display screen design with new color scheme.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

    a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

    b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.