SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
ZHENG ZHE
ENGINEER OF TECHNICAL REGULATION DEPARTMENT
MINDRAY BUILDING, KEJI 12TH RD SOUTH,
HI-TECH INDUSTRIAL PARK,
NANSHAN, SHENZHEN, 518057 P.R. CHINA

Re: K160370
Trade/Device Name: BS-800M/ ABS800/BA-800M ISE KIT
BS-800M Chemistry Analyzer
BA-800M Chemistry Analyzer
ABS-800 Chemistry Analyzer

Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: II
Product Code: JGS, CGZ, CEM, CDQ, JJE
Dated: April 15, 2016
Received: May 2, 2016

Dear Zeng Zhe:

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 Parts 801 and 809); medical device reporting (reporting of

June 9, 2016
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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Katherine Serrano -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

The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na⁺ (sodium), K⁺ (potassium), Cl⁻ (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

The BS-800M/ABS800/BA-800M ISE Kit is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum, plasma and urine samples on the The BS-800M/ABS800/BA-800M Chemistry Analyzer.

Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney function and other diseases associated with protein catabolism.
510(K) SUMMARY

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.

The assigned 510(k) number is: K160370.

Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888
Fax: +86 755 2658 2680

● Contact Person:

Zeng Zhe
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

● Date Prepared:

June 2, 2016

Name of the device:

● Trade/Proprietary Name:

BS-800M Chemistry Analyzer, BA-800M Chemistry Analyzer, ABS800 Chemistry Analyzer, BS-800M/ABS800/BA-800M ISE Kit
(BS-800M, BA-800M and ABS800 are the same analyzers except the appearance, logo and name of the models. For convenience of explanation, the BS-800M Chemistry Analyzer is represented of the three in this summary.)

● Common Name: Clinical Chemistry Analyzer (with optional ISE Module)

● Classification Number/Class:

75JJE, Class I
75CDQ, Class II
Legally Marketed Predicate Device:

K072018
BS-200 Chemistry Analyzer, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

K972671
BUN (LIQUID) REAGENT SET, POINTE SCIENTIFIC, INC.

Description:

The BS-800M/BA-800M/ABS800 Chemistry Analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The BUN (LIQUID) REAGENT SET was cleared under K972671 and is the chosen assay to demonstrate performance for the photometric unit. The BS-800M Chemistry Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using ion selective electrode technology.

Intended Use/ Indication for Use:

The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na+(sodium), K+ (potassium), Cl- (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction. The BS-800M/ABS800/BA-800M ISE Kit is for the in vitro quantitative determination of Sodium (Na+), Potassium (K+), and Chloride (Cl-) concentrations in serum, plasma and urine samples on the BS-800M/ABS800/BA-800M Chemistry Analyzer. Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders. Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney function and other diseases associated with protein catabolism.
Comparison of Technological Characteristics:

Substantial equivalence has been demonstrated between the BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer. Both of them utilize absorbance photometry to perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. The BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer both utilize Ion-Selective Electrodes technology to measures the concentration of the electrolytes, sodium, potassium, and chloride in samples.

Comparison Table of BS-800M and Predicate Device:

<table>
<thead>
<tr>
<th>Comparison Section</th>
<th>BS-800M</th>
<th>BS-200</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(K) Number</td>
<td>K160370</td>
<td>K072018</td>
</tr>
<tr>
<td>Intended use</td>
<td>The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na⁺ (sodium), K⁺ (potassium), Cl⁻ (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.</td>
<td>The BS-200 Chemistry Analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na⁺ (sodium), K⁺ (potassium), Cl⁻ (chloride) in serum, plasma and urine samples and Glucose in serum samples. Additionally, other various chemistry assays may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.</td>
</tr>
<tr>
<td>Parameter(photometric)</td>
<td>BUN</td>
<td>BUN</td>
</tr>
<tr>
<td>Parameter(ion selective electrode)</td>
<td>Na⁺, K⁺, Cl⁻</td>
<td>Na⁺, K⁺, Cl⁻</td>
</tr>
</tbody>
</table>

Comparison on photometric assay Chart 1: BS-800M and BS-200 analyzer

<table>
<thead>
<tr>
<th>Feature</th>
<th>BS-800M</th>
<th>BS-200 (Predicate Device)</th>
<th>Same (S)/Different (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(K)</td>
<td>K160370</td>
<td>K072018</td>
<td>/</td>
</tr>
</tbody>
</table>
1 **System Function**

<table>
<thead>
<tr>
<th></th>
<th>Automatic, computer controlled</th>
<th>Automatic, microprocessor controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LIS external connectivity capability</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Calibration/QC</strong></td>
<td>Automatic and Manual calibration/QC</td>
<td>Automatic and Manual calibration/QC</td>
</tr>
<tr>
<td><strong>Barcode</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

2 **Throughput (Max)**

<table>
<thead>
<tr>
<th></th>
<th>800 photometric tests per hour</th>
<th>200 photometric tests per hour</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1200 tests per hour with ISE</td>
<td>330 tests per hour with ISE</td>
</tr>
</tbody>
</table>

3 **Configuration**

<table>
<thead>
<tr>
<th></th>
<th>Analyzing unit, the Rack Feeder System, Operation unit, Output unit</th>
<th>Analytical unit, Operation unit, Output unit</th>
</tr>
</thead>
</table>

4 **Principle of Analysis**

<table>
<thead>
<tr>
<th></th>
<th>Photometric</th>
<th>Photometric</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analytical methods</strong></td>
<td>Endpoint</td>
<td>Endpoint</td>
</tr>
<tr>
<td></td>
<td>Fixed-time</td>
<td>Fixed-time</td>
</tr>
<tr>
<td></td>
<td>Kinetic</td>
<td>Kinetic</td>
</tr>
<tr>
<td><strong>Calibration methods</strong></td>
<td>Linear calibration and nonlinear calibration</td>
<td>Linear calibration and nonlinear calibration</td>
</tr>
</tbody>
</table>

5 **Optical Measurement Unit**

<table>
<thead>
<tr>
<th></th>
<th>Absorbance</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement Modes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Optical Modes</strong></td>
<td>Monochromatic, Bichromatic</td>
<td>Monochromatic, Bichromatic</td>
</tr>
<tr>
<td><strong>Photometer</strong></td>
<td>Multi-wavelength, diffraction grating spectrophotometer</td>
<td>Multi-wavelength, Light transmission mode of the filter</td>
</tr>
<tr>
<td><strong>Wavelength</strong></td>
<td>340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm, 700nm, 740nm and 800nm</td>
<td>340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, 670nm</td>
</tr>
<tr>
<td><strong>Linear absorbance range</strong></td>
<td>0-3.4 absorbance</td>
<td>0-4.0 absorbance</td>
</tr>
<tr>
<td><strong>Light Source</strong></td>
<td>Tungsten halogen lamp</td>
<td>Tungsten halogen lamp</td>
</tr>
<tr>
<td><strong>Detector</strong></td>
<td>Photodiode</td>
<td>Photodiode</td>
</tr>
</tbody>
</table>
## Reaction Unit

<table>
<thead>
<tr>
<th></th>
<th>Glass, 165 non-disposable</th>
<th>Plastic, 80 disposable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reaction cuvettes</strong></td>
<td>100~360µL</td>
<td>180~500µL</td>
</tr>
<tr>
<td><strong>Reaction volume</strong></td>
<td>5mm</td>
<td>5mm</td>
</tr>
<tr>
<td><strong>Optical path</strong></td>
<td>37°C</td>
<td>37°C</td>
</tr>
<tr>
<td><strong>Reaction temperature</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Sample and Reagent System

| Sample disk             | 140 positions. 45 positions respectively for outer two circles of outer rings and 25 positions respectively for inter two circles of inter rings | 40 sample tube positions on the outer circle |
| Reagent disk            | 120 positions. 50 positions for inner circle and 70 positions for outer circle. | 40 reagent bottle positions on the inner circle |
| Pipttor System          | Positive displacement stepper motor drive | Positive displacement stepper motor drive |
| Refrigerator temperature| 2-8°C | 4-15°C |
| Sample Dispense         | 1.5µL -50µL | 3µL -45µL |
| Reagent Dispense        | 15µL-300µL | 30µL-450µL |

## POWER

| Input                   | 110/115V±10%, 60Hz±1 | 100-130V±50/60±1 |
| Consumption             | 3800VA                | 1000 VA          |

## Operating environmental conditions

| Temperature              | 15°C to 30°C          | 15°C to 30°C  |
| Humidity                | 35% to 85%, non-condensing | 35% to 80%, non-condensing |

## Comparison on Electrolytes assay Chart 2: BS-800M ISE module and BS-200 ISE module

<table>
<thead>
<tr>
<th>Feature</th>
<th>BS-800M ISE Kit</th>
<th>BS-200 ISE Kit (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(K)</td>
<td>K160370</td>
<td>K072018</td>
</tr>
</tbody>
</table>

## Indication for use/Intended Use

<table>
<thead>
<tr>
<th>ISE Kit</th>
<th>The BS-800M/ABS800/BA-800M ISE Module is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum, plasma and urine samples on the BS-800M/ABS800/BA-800M Chemistry Analyzer.</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sodium</td>
<td>Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.</td>
</tr>
<tr>
<td>Potassium</td>
<td>Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.</td>
</tr>
<tr>
<td>Chloride</td>
<td>Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.</td>
</tr>
</tbody>
</table>

### 2 System Function

<table>
<thead>
<tr>
<th>Method Principle</th>
<th>Ion Selective Electrode</th>
<th>Ion Selective Electrode</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrode</td>
<td>Na⁺ electrode, K⁺ electrode, Cl⁻ electrode, reference electrode</td>
<td>Na⁺ electrode, K⁺ electrode, Cl⁻ electrode, reference electrode, Space electrode</td>
<td>D</td>
</tr>
<tr>
<td>ISE Internal Standard</td>
<td>None</td>
<td>None</td>
<td>S</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>22 µL total for all three tests</td>
<td>70 µL Serum, plasma mode; 140 µL Urine mode</td>
<td>D</td>
</tr>
<tr>
<td>ISE Throughput Rate</td>
<td>600 tests/hour</td>
<td>300 tests/hour Serum, plasma mode;</td>
<td>D</td>
</tr>
<tr>
<td>Test Environment</td>
<td>198 tests/hour Urine mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>--------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Lab</td>
<td>Clinical Lab</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3 Calibration

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>MR Serum Standard for Serum, Plasma mode; MR Urine standard for Urine mode;</th>
<th>ISE reagent pack for all three sample types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardization</td>
<td>Na: NIST standard material SRM919</td>
<td>Na: NIST standard material SRM956</td>
</tr>
<tr>
<td></td>
<td>K: NIST standard material SRM 918</td>
<td>K: NIST standard material SRM 956</td>
</tr>
<tr>
<td></td>
<td>Cl: NIST standard material SRM 919</td>
<td>Cl: NIST standard material SRM 956</td>
</tr>
<tr>
<td>Calibrator Stability</td>
<td>5°C~35°C, 12 months of shelf-life, 8 weeks of in-use stability</td>
<td>4°C~25°C, 24 months of shelf-life</td>
</tr>
<tr>
<td>Calibrator Matrix</td>
<td>Buffered Aqueous matrix</td>
<td>Buffered Aqueous matrix</td>
</tr>
<tr>
<td>Calibrator Form</td>
<td>liquid</td>
<td>liquid</td>
</tr>
<tr>
<td>Number of Calibrator levels</td>
<td>Two for serum/Plasma and Two for Urine</td>
<td>Two for serum/plasma/urine</td>
</tr>
<tr>
<td>Calibration Frequency</td>
<td>Daily</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

### 4 Performance Characters

<table>
<thead>
<tr>
<th>Analytical Measuring (mmol/L)</th>
<th>Serum/Plasma</th>
<th>Serum/Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Na: 100-200</td>
<td>Na: 113-194</td>
</tr>
<tr>
<td></td>
<td>K: 1-8</td>
<td>K: 1.1-8.6</td>
</tr>
<tr>
<td></td>
<td>Cl: 50-150</td>
<td>Cl: 53-154</td>
</tr>
<tr>
<td>Urine</td>
<td>Na: 10-400</td>
<td>Na: 27-372</td>
</tr>
<tr>
<td></td>
<td>K: 5-200</td>
<td>K: 13-184</td>
</tr>
<tr>
<td></td>
<td>Cl: 15-400</td>
<td>Cl: 42-422</td>
</tr>
<tr>
<td>Reference Interval</td>
<td>Serum(Adults):</td>
<td>Serum(Adults):</td>
</tr>
<tr>
<td></td>
<td>Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L</td>
<td>Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Plasma(Adults):</td>
<td>Plasma(Adults):</td>
</tr>
<tr>
<td></td>
<td>Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L</td>
<td>Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L</td>
</tr>
</tbody>
</table>

| Urine, 24 hour (Adults):     | Serum(Adults): | Serum(Adults): |
|                              | Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L | Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L |
|                              | Plasma(Adults): | Plasma(Adults): |
|                              | Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L | Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L |
|                              | Urine, 24 hour (Adults): | Urine, 24 hour (Adults): |
|                              | Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L | Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L |
|                              | Plasma(Adults): | Plasma(Adults): |
|                              | Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L | Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L |
### NSI Interferences

<table>
<thead>
<tr>
<th>NSI Interferences</th>
<th>Bilirubin</th>
<th>Na/K/Cl for three sample types: 40 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hemoglobin</td>
<td>Na/Cl for three sample types: 500 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Lipemia</td>
<td>Na/K/Cl for three sample types: 1000 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Ascorbic acid</td>
<td>Na/K/Cl for three sample types: 30 mg/dL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bilirubin</th>
<th>Na/K/Cl for three sample types: 20 mg/dL</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin</th>
<th>Na/K/Cl for three sample types: 500 mg/dL</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Lipemia</th>
<th>Na/K/Cl for three sample types: 1000 mg/dL</th>
</tr>
</thead>
</table>

### Performance Characteristics:

Performance testing of the BS-800M Chemistry Analyzer consisted of running the FDA previously cleared assay and the ISE module on the BS-800M to evaluate precision, linearity, and method comparison, Limits of Detection and Limits of Quantitation, interference, ISE plasma sample type studies.

A correlation analysis between the BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer yielded the following results:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Sample Range</th>
<th>N</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>5.4-149.5</td>
<td>122</td>
<td>0.98</td>
<td>0.81</td>
<td>0.9997</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>mmol/L</td>
<td>100.2-196.4</td>
<td>124</td>
<td>1.03</td>
<td>-5.95</td>
<td>0.9966</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>mmol/L</td>
<td>1.40-7.70</td>
<td>121</td>
<td>1.04</td>
<td>-0.09</td>
<td>0.9994</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>mmol/L</td>
<td>50.4-149.4</td>
<td>124</td>
<td>1.00</td>
<td>0.15</td>
<td>0.9993</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>mmol/L</td>
<td>12.1-395.4</td>
<td>120</td>
<td>0.99</td>
<td>-2.52</td>
<td>0.9997</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>mmol/L</td>
<td>5.1-194.7</td>
<td>120</td>
<td>0.98</td>
<td>-1.00</td>
<td>0.9997</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>mmol/L</td>
<td>15.2-381.3</td>
<td>120</td>
<td>0.97</td>
<td>2.06</td>
<td>0.9988</td>
</tr>
</tbody>
</table>

And the bias at the medical decision points of method comparison yielded the following...
results:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Medical decision points</th>
<th>Bias at the medical decision points (Difference/Difference%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Point 1</td>
</tr>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>6,26,50</td>
<td>0.696/11.6%</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>mmol/L</td>
<td>115,135,150</td>
<td>-2.713/-2.4%</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>mmol/L</td>
<td>3.0,5,8,7.5</td>
<td>0.032/1.1%</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>mmol/L</td>
<td>90,112</td>
<td>0.245/0.3%</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>mmol/L</td>
<td>40,112</td>
<td>-2.759/-6.9%</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>mmol/L</td>
<td>25,125</td>
<td>-1.418/-5.7%</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>mmol/L</td>
<td>110,250</td>
<td>-1.112/-1.0%</td>
</tr>
</tbody>
</table>

The total precision test of BS-800M yielded the following results:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Sample</th>
<th>n</th>
<th>Mean</th>
<th>Repeatability</th>
<th>Within-Device Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SD  CV%</td>
<td>SD  CV%</td>
</tr>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>Control pool 1</td>
<td>80</td>
<td>11.0</td>
<td>0.28 2.5%</td>
<td>0.33 3.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control pool 2</td>
<td>80</td>
<td>46.4</td>
<td>0.57 1.2%</td>
<td>0.94 2.0%</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>mmol/L</td>
<td>Control pool 1</td>
<td>80</td>
<td>136.1</td>
<td>0.35 0.3%</td>
<td>0.83 0.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control pool 2</td>
<td>80</td>
<td>166.1</td>
<td>0.46 0.3%</td>
<td>1.12 0.7%</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>mmol/L</td>
<td>Control pool 1</td>
<td>80</td>
<td>3.72</td>
<td>0.006 0.2%</td>
<td>0.021 0.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control pool 2</td>
<td>80</td>
<td>6.10</td>
<td>0.013 0.2%</td>
<td>0.033 0.5%</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>mmol/L</td>
<td>Control pool 1</td>
<td>80</td>
<td>89.4</td>
<td>0.21 0.2%</td>
<td>0.38 0.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>80</td>
<td>107.5</td>
<td>0.23 0.2%</td>
<td>0.44 0.4%</td>
</tr>
<tr>
<td>Analyte</td>
<td>Unit</td>
<td>Slope</td>
<td>Intercept</td>
<td>Correlation Coefficient</td>
<td>Linear Range Tested</td>
<td>Claimed Linear Range</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------</td>
<td>---------</td>
<td>-----------</td>
<td>-------------------------</td>
<td>---------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>0.9999</td>
<td>0.0053</td>
<td>0.9996</td>
<td>4.5-162.6</td>
<td>5-150</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>mmol/L</td>
<td>0.9996</td>
<td>0.0783</td>
<td>1.0000</td>
<td>41.9-224.4</td>
<td>100-200</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>mmol/L</td>
<td>0.9997</td>
<td>-0.0003</td>
<td>0.9999</td>
<td>0.61-9.34</td>
<td>1-8</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>mmol/L</td>
<td>0.9998</td>
<td>0.0389</td>
<td>0.9999</td>
<td>11.0-162.4</td>
<td>50-150</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>mmol/L</td>
<td>1.0000</td>
<td>0.0139</td>
<td>0.9999</td>
<td>7.5-469.5</td>
<td>10-400</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>mmol/L</td>
<td>1.0001</td>
<td>0.0175</td>
<td>0.9999</td>
<td>3.1-254.4</td>
<td>5-200</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>mmol/L</td>
<td>1.0000</td>
<td>0.0370</td>
<td>0.9999</td>
<td>10.9-439.4</td>
<td>15-400</td>
</tr>
</tbody>
</table>

The detection limit studies test of BS-800M yielded the following results:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>LoB</th>
<th>LoD</th>
<th>LoQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>0.4</td>
<td>0.9</td>
<td>4.2</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>mmol/L</td>
<td>1.9</td>
<td>3.5</td>
<td>39.5</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>mmol/L</td>
<td>0.04</td>
<td>0.05</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>Analyte concentration (mmol/L)</td>
<td>Bilirubin level (mg/dL)</td>
<td>Bias (mmol/L)</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------------------</td>
<td>-------------------------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>mmol/L</td>
<td>0.5</td>
<td>0.6</td>
<td>9.5</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>mmol/L</td>
<td>0.9</td>
<td>1.4</td>
<td>6.9</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>mmol/L</td>
<td>0.1</td>
<td>0.2</td>
<td>2.4</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>mmol/L</td>
<td>0.2</td>
<td>0.3</td>
<td>9.8</td>
</tr>
</tbody>
</table>

The Interference test of BS-800M yielded the following results:
Effects of bilirubin, hemoglobin, lipemia, ascorbic acid are tested, yielded the following results:

### Results of the bilirubin interference testing

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Analyte concentration (mmol/L)</th>
<th>Bilirubin level (mg/dL)</th>
<th>Bias (mmol/L)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>8.5 39.5</td>
<td>40</td>
<td>+0.0</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>134.0 154.8</td>
<td>40</td>
<td>-0.4  +0.4</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>3.23 5.94</td>
<td>40</td>
<td>-0.01  +0.00</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>89.7 114.7</td>
<td>40</td>
<td>-0.1  -0.2</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>45.9 224.1</td>
<td>40</td>
<td>+0.6  -1.3</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>26.9 127.3</td>
<td>40</td>
<td>+0.0  -0.4</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>113.9 253.5</td>
<td>40</td>
<td>+0.1  -1.5</td>
<td>NSI</td>
</tr>
</tbody>
</table>

### Results of the hemoglobin interference testing

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Analyte concentration (mmol/L)</th>
<th>Hemoglobin level (mg/dL)</th>
<th>Bias (mmol/L)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>8.6 40.0</td>
<td>500</td>
<td>+0.4  -0.1</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>129.4 153.1</td>
<td>500</td>
<td>+0.9  +0.9</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>3.15</td>
<td>≥250</td>
<td>+0.30</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>125</td>
<td>+0.61</td>
<td>SI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥250</td>
<td>+0.33</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>125</td>
<td>+0.68</td>
<td>SI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥250</td>
<td>+0.68</td>
<td>SI</td>
</tr>
<tr>
<td>Analyte</td>
<td>Analyte concentration (mmol/L)</td>
<td>Lipemia level (mg/dL)</td>
<td>Bias (mmol/L)</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------</td>
<td>-----------------------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>BUN</td>
<td>8.3</td>
<td>38.2</td>
<td>-1.2</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>125.3</td>
<td>147.6</td>
<td>-0.5</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>3.08</td>
<td>5.64</td>
<td>+0.05</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>85.5</td>
<td>111.5</td>
<td>+0.0</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine Na⁺</td>
<td>40.9</td>
<td>215.8</td>
<td>-0.1</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine K⁺</td>
<td>28.1</td>
<td>127.8</td>
<td>+0.1</td>
<td>NSI</td>
</tr>
<tr>
<td>Urine Cl⁻</td>
<td>110.8</td>
<td>232.9</td>
<td>-0.2</td>
<td>NSI</td>
</tr>
</tbody>
</table>

### Results of the ascorbic acid interference testing

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Analyte concentration (mmol/L)</th>
<th>Ascorbic Acid level (mg/dL)</th>
<th>Bias (mmol/L)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>9.0</td>
<td>30</td>
<td>-0.3</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Na⁺</td>
<td>132.9</td>
<td>153.4</td>
<td>-0.3</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum K⁺</td>
<td>3.19</td>
<td>5.89</td>
<td>+0.00</td>
<td>NSI</td>
</tr>
<tr>
<td>Serum Cl⁻</td>
<td>89.1</td>
<td>114.0</td>
<td>-0.2</td>
<td>NSI</td>
</tr>
</tbody>
</table>
There is no significant interference (NSI) observed when the concentrations of interference materials (including drugs) is below the ones in the following table:

<table>
<thead>
<tr>
<th>Interferents</th>
<th>Level tested(mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipemia</td>
<td>1000</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>40</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>30</td>
</tr>
<tr>
<td>Imipramine</td>
<td>0.15</td>
</tr>
<tr>
<td>Procainamide</td>
<td>15</td>
</tr>
<tr>
<td>Nortriptyline</td>
<td>0.26</td>
</tr>
<tr>
<td>Hydroxytyramine</td>
<td>50.7</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>512</td>
</tr>
<tr>
<td>Valproic acid</td>
<td>75</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>6</td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>72</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>1205</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>7.6</td>
</tr>
<tr>
<td>Ethosuximide</td>
<td>30.6</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>242</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>10.4</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>6</td>
</tr>
</tbody>
</table>

There was significant interference for hemoglobin and Potassium Thiocynate.

- Avoid Hemolyzed samples for potassium. Hemolyzed samples may give incorrect elevated potassium. Intracellular potassium concentration is 30-50 fold greater than that of extracellular serum or plasma.
- Potassium thiocynate increases potassium by 0.55 mmol/L at the concentration of 3.30 mmol/L and by 0.58 mmol/L at the concentration of 5.39 mmol/L.
- Potassium thiocynate increases chloride by12.3 mmol/L at the concentration of 90.9 mmol/L and by12.6 mmol/L at the concentration of 114.6 mmol/L.

The BS-800M’s sample type studies between serum and plasma of Na⁺, K⁺, Cl⁻ test yielded the following results, which proved the sample type plasma can also apply to ISE test:
<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>N</th>
<th>Sample Range</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>mmol/L</td>
<td>51</td>
<td>105.2-195.9</td>
<td>1.000</td>
<td>-0.33</td>
<td>0.9989</td>
</tr>
<tr>
<td>K⁺</td>
<td>mmol/L</td>
<td>51</td>
<td>1.45-7.87</td>
<td>0.966</td>
<td>-0.13</td>
<td>0.9930</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>mmol/L</td>
<td>51</td>
<td>54.2-148.1</td>
<td>0.996</td>
<td>0.62</td>
<td>0.9997</td>
</tr>
</tbody>
</table>

**Conclusion:**

The data demonstrates that the BS-800M Chemistry Analyzer is substantially equivalent to BS-200 Chemistry Analyzer.