510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k160370

B. Purpose for Submission:

Adding a previously cleared assay (BUN-k972671) on a new instrument, and clearance of a new ISE kit

C. Measurand:

Sodium, Potassium, Chloride and Urea Nitrogen

D. Type of Test:

Quantitative, Photometric and Ion Selective Electrodes

E. Applicant:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd

F. Proprietary and Established Names:

BS-800M Chemistry Analyzer
BA-800M Chemistry Analyzer
ABS-800 Chemistry Analyzer
BS-800M/ ABS800/BA-800M ISE Kit

G. Regulatory Information:

Product Code	Regulation Name	Classification	Regulation Section	Panel
CGZ	Chloride test system	II	21CFR 862.1170	Chemistry (75)
CEM	Potassium test system	II	21CFR 862.1600	Chemistry (75)
JGS	Sodium test system	II	21CFR 862.1665	Chemistry (75)
CDQ	Urea nitrogen test system	II	21CFR 862.1770	Chemistry (75)
JJE	Discrete Photometric Chemistry Analyzer for Clinical Use	I, exempt	21CFR 862.2160	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use

2. Indication(s) 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.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   BS-800M/BA-800-M/ABS8000 Chemistry Analyzer

   These three analyzers are different models of the same chemistry analyzer and they only differ in appearance and logo on the instruments. The BS-800M Chemistry Analyzer is selected to represent the three analyzers in this 510(k) submission.

I. Device Description:

The BS-800M/BA-800M/ABS800 Chemistry Analyzers are automated clinical chemistry analyzers utilizing photometric and ion selective electrode technology for clinical use. The Urea Nitrogen (BUN) (previously cleared in k972671) is chosen to demonstrate performance of the photometric unit. The ISE unit measures sodium, potassium and chloride utilizing ion selective electrode technology, and consists of the following:

1. BUN reagent contains the following:
   - Working reagent concentrations: Urease (Jack Bean) 15,000 U/L GLDH (Bovine)> 200 U/L, ADP > 0.6 mM, α-Ketoglutarate 3.6 mM, NADH > 0.28mM, Buffer, pH 7.8 + 0.1, Sodium Azide (0.25%) as preservative.

2. ISE module contains the ion-selective electrodes for sodium, potassium, chloride and a reference electrode, plus the following reagents:

   - MR serum standard - Components: Sodium Chloride (120 and 160 mmol/L), Potassium Chloride (3.5 and 6.0 mmol/L), Deionized Water, Surfactant and Preservatives.
   - MR urine standard - Components: Sodium Chloride (50 and 200 mmol/L), Potassium Chloride (10 and 100 mmol/L), Deionized Water, Surfactant and Preservatives.
   - MR Buffer Solutions - Components: Formaldehyde: < 1.0 w/v% and Phosphoric acid: < 1.0 w/v%.
   - MR Na/K Check Solution- Components: Sodium Chloride, Potassium Chloride,
   - Deionized Water, Surfactant and Preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   BS-200 Chemistry Analyzer with ISE Module
   Pointe Scientific BUN (Liquid) Reagent Set

2. Predicate 510(k) number(s):
   k072018
   k972671

3. Comparison with predicate:

1. Comparison of BS-800M with ISE module and BS-200 with ISE module

Item	Candidate Device:BS-800M Chemistry Analyzer with ISE	Predicate Device: BS-200 Chemistry Analyzer with ISE k072018
Intended Use		
Intended 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. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.	Same
System Function		
Method	Ion Selective Electrode	Same
Electrode	Na+ electrode, K+ electrode, Cl- electrode, reference electrode	Na+ electrode, K+ electrode, Cl- electrode, reference electrode, Space electrode
Reference reagent	MR Serum Standard, MR Urine Standard, MR Buffer Solution, MR Detergent Solution, MR Na/K Check Solution	Reagent Pack, Urine Diluent, Cleaning Solution
ISE Internal Standard	None	Same
Sample Volume	22 µL total for all three tests	70 µL Serum, plasma mode; 140 µL Urine mode
ISE Throughput Rate	600 tests/hour	300 tests/hour Serum, plasma mode; 198 tests/hour Urine mode
Test Environment	Clinical Lab	Same
Calibration		
Calibrator	MR Serum Standard for Serum, Plasma mode; MR Urine standard for Urine mode	ISE reagent pack for all three sample types

Standardization	Na: NIST standard material SRM 919 K: NIST standard material SRM 918 Cl: NIST standard material SRM 919	Na: NIST standard material SRM 956 K: NIST standard material SRM 956 Cl: NIST standard material SRM 956
Calibrator Stability	5℃~35℃, 12 months of shelf-life, 8 weeks of in-use stability	4℃~25℃, 24 months of shelf-life
Calibrator Matrix	Buffered Aqueous matrix	Same
Calibrator Form	liquid	Same
Number of Calibrator levels	Two for serum/Plasma and Two for Urine	Same
Calibration Frequency	Daily	8 hours
Performance Characters		
Analytical Measuring (mmol/L)	Serum/Plasma Na: 100-200, K: 1-8, Cl: 50-150 Urine Na: 10-400,K: 5-200, Cl: 15-400	Serum/Plasma Na: 113-194, K: 1.1-8.6, Cl: 53-154 Urine Na: 27-372, K: 13-184, Cl: 42-422
Reference Interval	Serum(Adults): Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L Plasma(Adults): Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L Urine, 24 hour (Adults): Sodium: 40-220 mmol/24h Potassium:25-125 mol/24h, Chloride:110-250 mol/24h	Serum(Adults): Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L Plasma(Adults): Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L Urine, 24 hour (Adults): Sodium: 40-220 mmol/24h Potassium:25-125 mol/24h Chloride:110-250 mol/24h

NSI Interferences concentration	Bilirubin- Na/K/Cl for three sample types: 40 mg/dL Hemoglobin- Na/Cl for three sample types: 500 mg/dL, Urine K: 500 mg/dL Lipemia- Na/K/Cl for three sample types: 1000 mg/dL Ascorbic acid- Na/K/Cl for three sample types: 30 mg/dL	Bilirubin -Na/K/Cl for three sample types: 20 mg/dL Hemoglobin- Na/K/Cl for three sample types: 500 mg/dL Lipemia- Na/K/Cl for three sample types: 1000 mg/dL
Throughput (Max) of the analyzer functionality comparisons:		
	800 photometric tests per hour 1200 tests per hour with ISE	200 photometric tests per hour 330 tests per hour with ISE
Configuration		
	Analyzing unit, the Rack Feeder System, Operation unit, Output unit	Analytical unit, Operation unit, Output unit
Principle of Analysis		
Mode of detection	Photometric	Same
Analytical methods	Endpoint Fixed-time	Same
Calibration methods	Linear calibration and nonlinear calibration	Same
Optical Measurement Unit		
Measurement Modes	Absorbance	Same
Optical Modes	Monochromatic, bichromatic	Same
Photometer	Multi-wavelength, diffraction grating spectrophotometer	Multi-wavelength, Light transmission mode of the Filter
Wavelength	340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm,	340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, 670nm
Linear absorbance	0-3.4 absorbance	0-4.0 absorbance
Light Source	Tungsten halogen lamp	Same

Detector	Photodiode	Same
Reaction Unit		
Reaction cuvettes	Glass, 165 non-disposable	Plastic, 80 disposable
Reaction volume	100~360μL	180~500μL
Optical path	5mm	Same
Reaction	37°C	Same
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	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
Pipettor System	Positive displacement stepper motor driven	Same
Refrigerator	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 Hz	100-130V～,50/60±1 Hz
Consumption	3800VA	1000 VA
Operating environmental conditions		
Temperature	15ºC to 30ºC	Same
Humidity	35% to 85%, non-condensing	Same

2. Comparison of the BUN test system:

Similarities and difference		
Item	Candidate Device of clearance of the Pointe Scientific BUN reagent	Predicate Device: Pointe Scientific BUN reagent k972671
Intended Use	For the quantitative in vitro determination of BUN in serum.	Same
Assay Method	Urease method	Same
Chemistry analyzer used	BS-800M/BA-800M/ABS800 Chemistry analyzers	ACE Schiapparelli chemistry analyzer
Sample Type	Serum	Same

K. Standard/Guidance Document Referenced (if applicable):

CLSI-EP5-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline- Third Edition.

CLSI-EP6-A. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI-EP9-A3. Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline- third Edition.

CLSI- EP7-A2. Interference Testing in Clinical Chemistry; Approved Guideline- Second Edition.

CLSI- EP17-A2. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second edition.

L. Test Principle:

BUN-Urea is hydrolyzed by urease to produce ammonia and carbon dioxide. The liberated ammonia reacts with α-ketoglutarate in the presence of NADH to yield glutamate. An equimolar quantity of NADH undergoes oxidation during the reaction resulting in a decrease in absorbance that is directly proportional to the urea nitrogen concentration in the sample.

ISE- The ion selective electrodes develop a voltage that varies with the concentration of the ion to which it responds, through the contact with samples. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nernst equation. Then the concentration of the ion (sodium, potassium, and chloride concentration in serum and plasma samples) can be calculated by the Nernst equation and the parameters obtained from the ISE testing process.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studied were performed according to CLSI document EP5-A3. Repeatability and total precision of serum BUN, serum Na, K and Cl, and urine Na, K and Cl were demonstrated by analyzing two levels of serum and urine based controls on the BS-800M Chemistry Analyzer. The control pools were analyzed in 20 replicates in one run for each analyte to obtain the within run precision (N=20). Two levels of serum and urine based controls were tested in duplicate twice per day for 20 days to obtain the total precision (N=80). Results are summarized in the tables below:

Analyte	Sample	Mean (mmol/L)	Repeatability		Total (Within Device) Precision	
			SD	CV%	SD	CV%
BUN (mg/dL)	Control pool 1	11.0	0.28	2.5%	0.33	3.0%
	Control pool 2	46.4	0.57	1.2%	0.94	2.0 %
Serum Na^+	Control pool 1	136.1	0.35	0.3%	0.83	0.6%
	Control pool 2	166.1	0.46	0.3%	1.12	0.7%
Serum K^+	Control pool 1	3.72	0.006	0.2%	0.021	0.6%
	Control pool 2	6.10	0.013	0.2%	0.033	0.5%
Serum Cl^-	Control pool 1	89.4	0.21	0.2%	0.38	0.4%
	Control pool 2	107.5	0.23	0.2%	0.44	0.4%
Urine Na^+	Control pool 1	87.1	0.22	0.3%	0.44	0.5%
	Control pool 2	148.6	0.36	0.2%	0.74	0.5%

Analyte	Sample	Mean (mmol/L)	Repeatability		Total (Within Device) Precision	
			SD	CV%	SD	CV%
Urine K^+	Control pool 1	35.1	0.08	0.2%	0.21	0.6%
	Control pool 2	68.8	0.16	0.2%	0.41	0.6%
Urine Cl^-	Control pool 1	90.4	0.20	0.2%	0.40	0.4%
	Control pool 2	133.9	0.17	0.1%	0.48	0.4%

b. Linearity/assay reportable range:

The linearity studies were performed followed the CLSI EP06-A guidance. Eleven equally spaced samples covering the measurement range were prepared by mixing high and low concentration samples. Four replicates were measured for each sample. The results are summarized in the table below:

Analyte	Slope	Intercept	R^2	Linear Range Tested (mg/dL for BUN and mmol/L for ISE)	Claimed Measuring range
BUN	0.9999	0.0053	0.9996	4.5-162.6	5-150
Serum Na+	0.9996	0.0783	1.0000	41.9-224.4	100-200
Serum K+	0.9997	-0.0003	0.9999	0.61-9.34	1-8
Serum Cl-	0.9998	0.0389	0.9999	11.0-162.4	50-150
Urine Na+	1.0000	0.0139	0.9999	7.5-469.5	10-400
Urine K+	1.0001	0.0175	0.9999	3.1-254.4	5-200
Urine Cl-	1.0000	0.0370	0.9999	10.9-439.4	15-400

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

Each electrolyte's traceability information is shown below.

Analyte	Reference methods/materials
Na	Atomic absorption method (NIST standard material SRM919)
K	Atomic absorption method (NIST standard material SRM918)
Cl	Atomic absorption method (NIST standard material SRM919)

Traceability for BUN reagent is to NIST BUN standard and was established under k972671.

Stability

MR Serum/Urine Standards are stable for 12 months when stored at 5°C~35°C and protected from light. Once opened, MR Serum/Urine Standards are stable for 8 weeks when stored tightly capped at 5°C ~35°C and protected from light. The protocols for stability and acceptance criteria were reviewed and found to be adequate. BUN reagent stability was evaluated under k972671. Closed vial stability is at 2-8°Cand open vial stability is 3 days at 18-25°C and 14 days at 2-8°C.

Value assignment

The MR Serum Standards (High/Low levels) and MR Urine Standards (High/Low levels) consist of Sodium Chloride, Potassium Chloride, Deionized Water, Surfactant and Preservatives. The calibrator values are assigned internally following a traceability process based on EN ISO 17511.

The target values are shown in the tables below:

MR Serum Standards	Na^+	K^+	Cl^-
High level (mmol/L)	160	6.0	120
Low level (mmol/L)	120	3.5	85
MR Urine Standards	Na^+	K^+	Cl^-
High level (mmol/L)	200	100	180
Low level (mmol/L)	50	10	50

The value assignment procedures for calibrators and controls of BUN Test System have been previously evaluated under k070207 and k042318.

d. Detection limit:

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) were evaluated in accordance with CLSI EP17-A2 Guideline using the BS-

800M Chemistry Analyzer.

LoB was determined by testing five blank samples using two reagent lots over three days. Every sample was assayed in four replicates per reagent lot per day. A total of 60 measurements were obtained per reagent lot.

LoD was determined by testing five low level samples using two reagent lots over three days. In total 60 measurements were obtained per reagent lot.

In the LoQ studies, five low level samples of known measurand concentration are prepared. The BUN and serum Na+, K+ and Cl- concentration is obtained from dilution calculation with SRM 956d and SRM 909c whose measurand concentration is determined by NIST. And urine Na+, K+ and Cl- concentration is obtained from dilution calculation with salt solution whose measurand concentration is determined by theoretical spike. All samples were assayed in four replicates per reagent lot per day for three days.

Results are summarized in the table below.

Analyte	Unit	LoB	LoD	LoQ	Claimed Measurement Range
BUN	mg/dL	0.4	0.9	4.2	5-150
Serum Na+	mmol/L	1.9	3.5	39.5	100-200
Serum K+	mmol/L	0.04	0.05	0.54	1-8
Serum Cl-	mmol/L	0.5	0.6	9.5	50-150
Urine Na+	mmol/L	0.9	1.4	6.9	10-400
Urine K+	mmol/L	0.1	0.2	2.4	5-200
Urine Cl-	mmol/L	0.2	0.3	9.8	15-400

e. Analytical specificity:

Interference studies are carried out according to the CLSI EP7-A2 guideline.

Interference studies were performed to determine the effects from potential interferents such as bilirubin, hemoglobin, lipemia, ascorbic acid, drugs on the BUN and the ISE assays using the BS-800M Chemistry Analyzer. Multiple levels of interference were tested for each analyte. The sponsor states that interference is considered to be non-significant if the bias between the tested and control samples are within +/-10%. The highest endogenous substance concentration tested that shows non-significant interference are summarized below:

Item	Highest Concentration Tested that showed no significant interference			
	Total Bilirubin (mg/dL)	Hemoglobin (mg/dL)	Lipemia (mg/dL)	Ascorbic Acid (mg/dL)
Serum BUN	40	500	750	30
Serum Na+	40	500	1000	30
Serum K+	40	*	1000	30
Serum Cl-	40	500	1000	30
Urine Na+	40	500	1000	30
Urine K+	40	500	1000	30
Urine Cl-	40	500	1000	30

* Hemolysis can lead to falsely elevated K+ values.

The highest exogenous substance concentration tested that shows non-significant interference are summarized below.

Drug Interferents	Drug Level tested(mg/dL)
Imipramine	0.15
Procainamide	15
Nortriptyline	0.26
Hydroxytyramine	50.7
Ibuprofen	512
Valproic acid	75
Chlorpromazine	6
Salicylic acid	72
Acetylsalicylic acid	1205
Erythromycin	7.6
Ethosuximide	30.6
Acetaminophen	242
Benzalkonium Chloride	10.4
Ampicillin	6

There was significant interference from Hemoglobin and Potassium thiocynate. The sponsor added the following limitations to their labeling:

- 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

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed according to CLSI document EP9-A3. 120- 124 samples for each analyte were assayed in duplicate on the BS-800M Chemistry Analyzer and the BS-200 Chemistry Analyzer (predicate device). Less than 10% of the samples were spiked or diluted to fully span the claimed measuring range of each analyte. The first of the duplicate results from the BS-800 chemistry analyzer were compared against the predicate's results. The Deming regression analysis results are shown in the table below.

Analyte	Sample Range Tested (mmol/L)	Claimed Linear Range	N	Slope	Intercept	Correlation Coefficient
Serum BUN	5.4-149.5 (mg/dL)	5-150	122	0.98	0.81	0.9997
Serum Na+	100.2-196.4	100-200	124	1.03	-5.95	0.9966
Serum K+	1.40-7.70	1-8	121	1.04	-0.09	0.9994
Serum Cl-	50.4-149.4	50-150	124	1.00	0.15	0.9993
Urine Na+	12.1-395.4	10-400	120	0.99	-2.52	0.9997
Urine K+	5.1-194.7	2-200	120	0.98	-1.00	0.9997
Urine Cl-	15.2-381.3	15-400	120	0.97	2.06	0.9988

b. Matrix comparison:

Serum and lithium heparin plasma equivalency was demonstrated for the Sodium, Potassium and Chloride assays on the BS-800M Chemistry Analyzer by testing 51 matched samples. Less than 10% of total samples were samples diluted with water or spiked with NaCl or KCl to span the assay ranges. One replicate of each sample was collected and used for the analyses. The table below summarizes the Deming linear regression results statistics when comparing lithium heparin plasma sample results to serum sample results:

Analyte	Unit	N	Sample Range	Slope	Intercept	Correlation Coefficient
Na+	mmol/L	51	105.2-195.9	1.000	-0.33	0.9989
K+	mmol/L	51	1.45-7.87	0.966	-0.13	0.9930
Cl-	mmol/L	51	54.2-148.1	0.996	0.62	0.9997

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable

   b. Clinical specificity:

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range[1]:

	Serum	Plasma	Urine (24 hour)
BUN	6 - 20 mg/L	--	--
Sodium	136-145 mmol/L	135-145 mmol/L	40-220 mmol/L
Potassium	3.5 – 5.0 mmol/L	3.5-4.5 mmol/L	25-125 mmol/L
Chloride	98-107 mmol/L	100-108 mmol/L	110-250 mmol/L

[1]*Tietz NW, editor: Fundamentals of clinical chemistry, 6th Edition, W.B. Saunders Co., Philadelphia, PA, 2008*

N. Instrument Name:

BS-800M Chemistry Analyzer, BA-800M Chemistry Analyzer, ABS800 Chemistry Analyzer

These three analyzers are different models of the same chemistry analyzers and they only differ in appearance and logo on the instruments. The BS-800M Chemistry Analyzer is selected to represent the three analyzers in this 510(k) submission.

O. System Descriptions:

1. Modes of Operation: Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___X_____

2. Software: FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   Barcode identification is available for specimen tubes and reagent bottles.

4. Specimen Sampling and Handling:

   The system supports manual and auto load of samples. The analyzing unit handles all analyzing operations, which include sample and reagent handling, mixing, reaction, measurements, cuvette wash station.

5. Calibration:

   The sponsor recommends BUN calibration frequency every 14 days or with change in reagent lot or as indicated by quality control procedures. This product has been previously cleared in k070207. The sponsor recommends user to perform an ISE Two-point calibration using fixed concentrations of MR Urine Standard and MR Serum Standard for the ISE module on BS-800M, ABS800, BA-800M Chemistry Analyzer.

6. Quality Control:

   The analyzer has a built in quality control program with two mode to run control samples, automatic or manual. The labeling recommends running control samples every time after the user perform a calibration, or change the reagent lot, or maintain and troubleshoot the instrument.

   The sponsor recommends in their labeling that QC materials should be run after each calibration of the ISE module. Controls should be run once each day of use. It is recommended that each laboratory establish their own frequency of control determination.

P. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Q. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.