

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE AND INSTRUMENT TEMPLATE**

**A. 510(k) Number:**

k040958

**B. Purpose for Submission:**

New device and instrument

**C. Analyte:**

Potassium, Chloride, Sodium

**D. Type of Test:**

Ion selective electrode – Potassium, Sodium, Chloride

**E. Applicant:**

Tokyo Boeki Medical Sytem Ltd.

**F. Proprietary and Established Names:**

Prestige 24i, Prestige 400, MGC 240 (These are the same models except the names)

**G. Regulatory Information:**

1. Regulation section:  
21 CFR 862.2160 Analyzer, Chemistry; 21 CFR 862.1600 Electrode, Ion Specific, Potassium; 21 CFR 862.1665 Electrode, Ion Specific, Sodium; 21 CFR 862.1170 Electrode, Ion Specific, Chloride; 21 CFR 862.1150 Calibrator, Multi-Analyte Mixture
2. Classification:  
Class I for Analyzer  
Class II for the others
3. Product Code:  
JJE; CEM; JGS; CGZ: JIX
4. Panel:  
75 Chemistry

**H. Intended Use:**

1. Intended use(s):  
Refer to Indications for Use
2. Indication(s) for use:  
This device with an optional Ion-selective Electrode (ISE) module is a clinical chemistry analyzer intended to be used for the measurement of sodium, potassium, and chloride in serum to monitor electrolyte balance.
3. Special condition for use statement(s):

None

4. Special instrument Requirements:

None

**I. Device Description:**

The Prestige 24i with Ion-Selective modules additionally measures the concentration of the electrolytes, sodium, potassium and chloride in samples, using indirect potentiometry.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Roche Cobas Mira Plus
2. Predicate K number(s):  
K851172
3. Comparison with predicate:

Similarities & Differences		
Item	Device	Predicate
Intended Use	The Prestige 24i is intended to be used for the measurement of sodium, potassium, and chloride in samples of whole serum, aqueous solutions as appropriate.	The Roche Diagnostics Cobas Mira Plus is intended to be used for the measurement of sodium, potassium, and chloride in samples of whole serum, aqueous solutions as appropriate.
Test Principle	Ion Selective Electrode	Ion Selective Electrode
Parameters Measured	Sodium, potassium, Chloride	Sodium, potassium, Chloride
Sample Type	Serum	Serum, Dialysis

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

Guidance for Industry In Vitro Diagnostic Chloride Test System  
 Guidance for Industry In Vitro Diagnostic Sodium Test System  
 Guidance for Industry In Vitro Diagnostic Potassium Test System

**L. Test Principle:**

Ion Selective Electrode

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. Precision/Reproducibility:  
 With-in-run precision was determined from 20 tests respectively on the Prestige 24i using Sample I (Stanbio Ser-T-fy I, Normal Control

Serum) and Sample II. (Stanbio Ser-T-fy II, Abnormal Control Serum) with the following results:

	Sample I	Sample I
Sodium (%CV)	1.0	0.6
Potassium (%CV)	1.7	1.0
Chloride (%CV)	0.5	0.8

Day-by-day precision was determined from one run per day for 20 days on the Prestige 24i using Sample I (Stanbio Ser-T-fy I, Normal Control Serum) and Sample II. (Stanbio Ser-T-fy II, Abnormal Control Serum) with the following results:

	Sample I	Sample I
Sodium (%CV)	1.4	1.3
Potassium (%CV)	1.5	1.3
Chloride (%CV)	2.5	2.3

b. *Linearity/assay reportable range:*

Testing was performed using NaCl (Sodium Chloride) solution and KCl (Potassium Chloride) solution of different concentration respectively. The linearity for each analyte was described as follows:

	Sodium	Potassium	Chloride
Correlation	0.9999	1.0000	1.0000
Slope	1.0272	0.9878	0.8988
Intercept	3.0436	0.0637	2.5806
Range	70-200 (mmol/L)	1-50 (mmol/L)	70-200 (mmol/L)

The serum measurement range of the ISE module will be adjusted into five or six steps in concentration, including the minimum value and the measured values will be compared with the theoretical values. The measurement range of serum

Sodium (Na) 70 – 200 mmol/L

Potassium (K) 1.0 – 20.0 mmol/L

Chloride (Cl) 70 – 200 mmol/L

Adjustment Method

1. Adjustment of undiluted solution

1-1. Adjustment for sodium chloride aqueous solution of 1 mol/L

Sodium chloride of 58.44g is weighed and put into the measuring flask of 1 liter. After that, it is dissolved by pure water and measured up.

1-2. Adjustment for sodium chloride aqueous solution of 0.1 mol/L

Sodium chloride of 7.455g is weighed and put into the measuring flask of 1 liter. After that, it is dissolved by pure water and measured up.

2. Adjustment of reagent of each concentration

2-1. Adjustment of reagent for sodium and chloride

Each volume of undiluted solution in the following table is measured out by a measuring pipette, and put into the measuring flask of 100mL, and dissolved by pure water to be measured up.

Concentration of sodium and chloride (mM)	0.0	50.0	70.0	100.0	140.0	200.0
Volume of undiluted solution of sodium chloride (mL)	0.0	5.0	7.0	10.0	14.0	20.0

2-2. Adjustment of reagent for potassium

Each volume of undiluted potassium in the following table is measured out by a measuring pipette, and put into the measuring flask of 100mL, and dissolved by pure water to be measured up.

Concentration of potassium (mM)	0.0	1.0	5.0	10.0	20.0
Volume of undiluted solution of potassium chloride (mL)	0.0	5.0	7.0	10.0	20.0

c. *Traceability (controls, calibrators, or method):*

Two points calibration is done every morning, before the system starts to operate. Calibrator 1 and Calibrator 2 were measured immediately after calibration was performed and every two by Prestige 24i to check the fluctuation of the data. The room temperature fluctuation was within 2 degree C. Calibrator 1 and Calibrator 2 for Prestige 24i ISE module is stable for one year in case of unopened and for 31 days after opened.

d. *Detection limit:*

Detection limits for the Prestige 24i are defined as the linear range of each assay. The minimum values obtained for each tested parameter are near the limit of detection for the system.

Sodium (Na)	Equal or less than 50mmol/L
Potassium (K)	Equal or less than 1.0mmol/L
Chloride (Cl)	Equal or less than 50mmol/L mmol/L

e. *Analytical specificity:*

Interference testing was performed to demonstrate the specificity of the Prestige 24i. The results from each of the studies were tabulated and the simple average effect was determined for each interfering compound. Those results demonstrate no interference with the sodium, potassium or chloride ISE tests when serum contains up to 18.4 mg/dL free

bilirubin , 19.7 mg/dL conjugated bilirubin, 1760 mg/dL lipid turbidity, or 490 mg/dL hemoglobin.

Interference by over the counter and prescription drugs are listed in the submission.

*f. Assay cut-off:*

The assay cut-off is established as the linearity range of the Prestige 24i for each analyte. The serum measurement range of the ISE module will be adjusted into five or six steps in concentration, including the maximum value and the measured values will be compared with the theoretical values. For the dilution series, approximate 200mmol/L will be 0/10.

Adjustment Method and Measurement Method:

The adjustment method and measurement method will follow the above mentioned methods. The measurable ranges will be determined by 95% of accuracy, comparing the maximum detection limits by errors or as the saturation and the theoretical values. The assay cut-off is established as the linearity range of the Prestige 24i (Prestige 400, MGC 240) for each analyte.

Sodium (Na)	Equal or more than 800mmol/L
Potassium (K)	Equal or more than 100mmol/L
Chloride (Cl)	Equal or more than 800mmol/L

2. Comparison studies:

*a. Method comparison with predicate device:*

Freshly collected serum samples (collected on the day the tests were run) were collected at an outside and run on the laboratory's clinical chemistry analyzer (Roche Cobas Mira Plus). Prior to running the specimens, calibration of the ISE electrodes took place and controls were run on analyzer to verify proper calibration. All ISE reagents, calibrators and controls were Roche branded products and all products were within their expiration dates before use. These same collected samples were transported to StanBio Laboratory immediately after testing on the Roche analyzer.

The Prestige ISE modules was properly calibrated and controls were run to verify the calibration. Tokyo Boeki ISE reagents and calibrator were used while StanBio brand of control (Normal & Abnormal) were used. After calibration verification and controls recoveries were conducted, the collected patient specimens were run on the Prestige 24i analyzer. The correlations to the predicate device are as follows:

Sodium:	$Y = 0.9488 X + 6.8625$	$r = 0.9744$	$n = 97$
Potassium :	$Y = 0.9813 X - 0.0135$	$r = 0.994$	$n = 97$
Chloride:	$Y = 0.9696 X + 3.2579$	$r = 0.985$	$n = 97$

*b. Matrix comparison:*

The Prestige 24i utilizes the same sample types – serum as the previously cleared on the predicated device, Cobas Mira Plus (K851172).

3. Clinical studies:

*a. Clinical sensitivity:*

None stated

*b. Clinical specificity:*

None stated

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

None

4. Clinical cut-off:

None stated

5. Expected values/Reference range:

	Chloride	Potassium	Sodium
Adult:	90 – 110 mEq/L	3.5 -5.0 mEq/L	136 – 145 mEq/L
Child:	90 – 110 mEq/L	3.4 – 4.7 mEq/L	136 – 145 mEq/L

**N. Instrument Name:**

Prestige 24i, Sirrus, MGC 240 (Same models except names)

**O. System Descriptions:**

1. Modes of Operation:

Discrete, Single line random access, multi-tests analysis

2. Software:

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

Yes   X   or No           

3. Sample Identification:

Bar code

4. Specimen Sampling and Handling:

Automatic sample aspiration

5. Assay Types:

The Prestige 24i uses measurement technology that is based on electrochemical phenomena. The device use potentiometry and amperometry methods for electrolytes to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that concentration of a specific analyte or substances in recognizable units of measurement.

6. Reaction Types:

Ion selective electrode for Chloride, Potassium, Sodium

7. Calibration:

Calibrators, Calibrator 1 and Calibrator2 are supplied by Tokyo Boeki. One point calibration is done for every test. Two point calibration is done every morning before the system starts to operate.

8. Quality Control:

Quality control target ranges are included with each lot of QC material. QC timing is established by the user via the user interface.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Determination Decision Summary:**

Not Applicable

**Q. Conclusion:**

The submitted material in this premarket notification is complete and support a substantial equivalence decision.